Sir,

We congratulate Dr Sharma and Dr Chaudhary for their case report, 'The opalescence of hydrogel intraocular lens', published recently in *Eye*.[1] These authors encountered 7 cases of intraocular lens (IOL) opalescence appearing about 6 months post-operatively. All the operated patients had uncomplicated phacoemulsification with an uneventful early post-operative period. The common factor in all 7 cases was the opacification of hydrogel IOL types. The authors did not mention the source/manufacturer(s) of lenses.

In the past 16 months we have also simultaneously and individually studied several hydrophilic optic acrylic foldable lenses explanted due to a delayed post-operative opacification.[2–8] The first group, the Bausch and Lomb (Rochester, NY, USA) Hydroview™ design, was characterised by a calcium precipitation on the IOL surfaces (Fig. 1).[3] (Werner L, Apple DJ, Pandey SK. 'Late postoperative opacification of 2 hydrophilic intraocular lens designs'; presented at the ASCRS Symposium on Cataract, IOL and Refractive Surgery, Best Paper of Session, San Diego, CA, 28 April 2001). We reported clinical, pathological and histochemical features of 5 Bausch and Lomb Hydroview™ IOLs explanted from 5 patients who had visual disturbances caused by post-operative deposits on the lens surfaces.[3,4] These studies, done independently of that of Drs Sharma and Chaudhary, were histopathological reports of calcified deposits on the surfaces of the IOL optic. In a separate study from China, Yu and Shek[9] also reported on a series of 3 cases with unexpected late post-operative opacification of the same model (Baush and Lomb Hydroview™ IOLs) due to hydroxyapatite formation. Although the precise mechanism is not fully understood, the manufacturer (Bausch and Lomb) has suggested that there is a correlation between a change in packaging and the appearance of opacification. In lenses placed into the current IOL packaging, trace amounts of low-molecular silicone have been detected on some IOL surfaces. The source of the silicone was determined to be the gasket used to seal the packaging vial.[2,6] The manufacturer now states that this problem is resolved. However, final verification will require a careful 1–2 year clinical study.

The second IOL design, which presented with an even more severe degree of opacification, was a single-piece hydrophilic acrylic IOL (model SC 60B-OUV) manufactured by Medical Developmental Research (MDR, Inc., Clearwater, FL, USA). We are aware of several hundred cases of lens opacification from various countries (Germany, UK, Turkey, France, China, India, Egypt, South Africa and others). We have received a total of 45 explanted single-piece hydrophilic acrylic IOLs, submitted to our Center for pathological evaluation (Fig. 2). Our clinicopathological study of 9 single-piece hydrophilic acrylic IOLs explanted secondary to development of opacification has recently been published.[8] The process of opacification appears to be related to degeneration of the UV filtration material[10] and/or deposits of calcium below the IOL optics' surface, within the substance of the optic biomaterial. In some cases, the entire optical component (and occasionally haptics) are completely opaque (Pandey SK, Werner L, Apple DJ, *et al.* 'Different patterns of calcium precipitation in the optic and haptics of foldable hydrophilic acrylic lenses'; presented at the ASCRS Symposium on Cataract, IOL and Refractive Surgery, San Diego, CA, 28 April 2001).

The polymer biomaterial of the single-piece hydrophilic acrylic IOL was formulated and prepared by Vista Optics (London, UK) and the lens was then manufactured by MDR Inc., Clearwater, FL, USA. The manufacturer (MDR Inc.) recommends all surgeons be aware of the problem and return all SC 60B-OUV lenses to the manufacturer. MDR's new second-generation single-piece design SC25B-OUV is manufactured from polymer material from a new source formulated and prepared by Benz Research, Sarasota, FL, USA. However, 1–2 year clinical tests will be necessary to determine whether this change proves useful.

Drs Sharma's and Chaudhary's work, which correlated with ours, provides an excellent example of classic clinicopathological correlation: a clinical report from their standpoint and independent pathological correlation from our facility. Because the work was done simultaneously in the two facilities working on opposite sides of the Atlantic, neither they nor we were able to cite each other's work. However, taken together the studies provide a necessary alert for surgeons implanting these lenses. Surgeons are encouraged to submit explanted IOLs to our laboratory in order to obtain a pathological perspective. Finally, it is important to carefully follow clinical outcomes of these opacified lenses in order to determine whether this phenomenon is rare and sporadic or possibly more widespread.

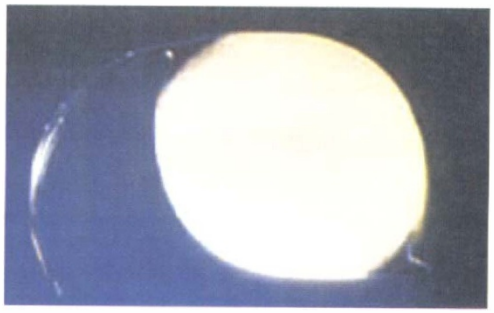

Fig. 1. *Gross photograph of one of the explanted Bausch and Lomb Hydroview™ lenses submitted to our laboratory by Dr Anne Öhrström of Vasteras, Sweden. Note the complete opacification of the lens optic. The IOL's haptics are not involved.*

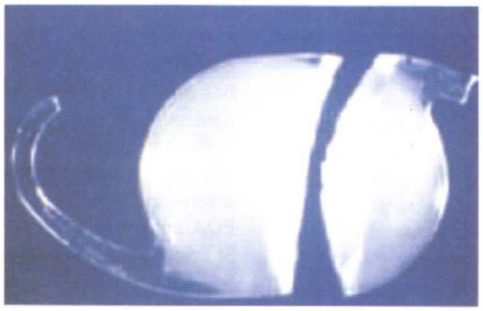

Fig. 2. *Gross photograph of one of the explanted single-piece SC60B-OUV lenses, manufactured by MDR, Inc., Clearwater, FL, USA. This opacified IOL was explanted after bisection and submitted to our laboratory by Dr Nitin Anand of Luton, UK. Note the opacity of the central optic area and a clear band approximately 1 mm wide subtending the optic. The IOL's haptics are also clear.*

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David J. Apple, MD ✉
Liliana Werner, MD PhD
Suresh K. Pandey, MD
Center for Research on Ocular Therapeutics and Biodevices
167 Ashley Avenue
PO Box 250676
Storm Eye Institute
Medical University of South Carolina
Charleston, SC-29425, USA
e-mail: appledj@musc.edu

Sir,

We thank Drs Apple, Werner and Pandey for their comments on our article.[1] A few articles in the last two years[2–5] have reported opalescence of acrylic intraocular lenses. Apple and colleagues have discussed various possible mechanisms for this opalescence put forward by manufacturers, other investigators and themselves. Isolated instances of discoloration (but not opacification) of silicone intraocular lenses have been published,[6] reporting brownish discoloration of intraocular lenses unlike the varying degree of milky-white opalescence recorded in hydrogel intraocular lenses. It is difficult to conceptualise how trace amounts of silicon contaminant on the surface of Bausch and Laumb Hydroview lenses could induce uniform calcification, which in some lenses was only inside the deeper layers of the lens. Yu and Shek[2] from China showed that opacification in their cases of Hydroview lenses was causd by compounds containing calcium and phosphorus, probably derived from aqueous. They were unable to explain the varying degrees of opacification in different patients. Our lenses, manufactured by Medical Development Research (MDR), Inc., of Clearwater, Florida (model no. SC60B-OUV), were made of medical-grade copolymer of hydrophilic acrylic with a polymerisable UV blocker. We have implanted 155 of these lenses, and had to explant 25 of them so far. The results of clinical study on visual functions of our patients have been presented (poster presented at the Annual Meeting of the Royal College of Ophthalmologists, 22–24 May 2001, Birmingham; results to be published).

We were the first to report this complication to the Medical Devices Agency, an executive agency of the Department of Health in the United Kingdom. We were formally informed by Dr Austin,[7] from the Implants and Materials Section of the agency, on 26 June 2001 that 'MDR has indicated that reports of clouding correlates to 4 batches of one of the raw materials used in the manufacture of these lenses. They believe that the levels of impurities present in the raw material interacted with calcium salts causing precipitation **on** the lens' (emphasis ours). We are still not convinced by this explanation as it fails to address why in some lenses the opacification is only in the deeper layer of the material, sparing the surface and superficial parts of the lens. These lenses carried a CE mark, which is a quality control parameter for Europe (this mark has now been withdrawn from these devices). We are shocked how ineffective this quality control parameter has proven in this instance. Interestingly, these lenses did not have FDA approval for use in the United States. At the ASCRS 2001 meeting at San Diego, in the film festival, Robert H. Osher's award-winning video entitled 'FDA or DWR' mocked the FDA for its restrictive and time-consuming certification process and jokingly called the FDA **F**or **D**evelopment **A**broad. We all laughed at this nomenclature but here the FDA has been proven right and the agencies in Europe, which award the CE mark, have been proven wanting.

We also wish to record our frustrations in finding an appropriate agency to independently investigate this problem for us. The Medical Devices Agency in London is not equipped with laboratory facilities to undertake this kind of an investigation. The other lens manufacturers would not want to get involved in an investigation on a competitor's lens, for reasons of conflict of interest. Thus the Medical Devices Agency had to rely on the manufacturing company itself to investigate the matter for them. We also wish MDR had been keener to talk to the surgeons, as one of us (S.C.) went personally to their stand to discuss the problem at the ASCRS meetings in Seattle (1999) and Boston (2001), after duly informing them of our intention weeks in advance.

Under these circumstances, we feel Professor Apple's Centre for Research on Ocular Therapeutics and Biodevices is a very timely venture. We are happy to extend our support to Apple and colleagues in an attempt to find the remaining answers to this problem.

The main message we wish to convey to clinicians the world over is that defects of intraocular devices on such a large scale can occur in this day and age. Surgeons should, therefore, minutely study the data before deciding to change their time-tested devices. Quality control markers such as, in this case, the CE mark can be fallible. Therefore, the tests employed by certifying agencies should be made more stringent so that the clinicians' confidence in such markers is restored.

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