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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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Sir,

I thoroughly enjoyed reading the article by Comer *et al*., 'Who should manage primary retinal detachments?'[1] This regional study was conducted in the early 1990s, and it documents the shift away from 'general' ophthalmologists treating retinal detachments towards greater success by a 'dedicated vitreoretinal (VR) unit'. I believe the debate has moved on since then and there are increasing numbers of vitreoretinal-trained DGH ophthalmologists who fall into neither of the above categories and who provide a comprehensive retinal detachment service locally. The audit for 1999/2000 in Ipswich demonstrated a primary success rate of 86.1% (31/36), falling within the high standards (85–90%) called for by Comer *et al*. Clinical governance will show which surgeons in which hospitals are falling significantly and consistently below standard. The 1997 national audit for primary retinal detachment surgery did not demonstrate any significant correlation between surgical success and annual case load amongst surgeons with a VR interest.[2] Is it necessary for VR surgeons to centralise in teaching hospitals in order to perform retinal detachment surgery? I believe the answer to be 'no'. There may be certain procedures which ought to be performed exclusively in such centres, but that is a different debate.

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Sir,

We read with interest the article by Comer *et al*., 'Who should manage primary retinal detachments?'[1] We congratulate them for closing their audit cycle. The authors have shown a significant improvement in success rate for primary retinal reattachment surgery since such procedures were mainly done in a specialist vitreoretinal unit (VRU). We would like to share our results of primary retinal detachment (RD) surgery from a general ophthalmic unit with no VR facilities.

A retrospective audit was done between 1 March 1995 and 1 March 1998 on 52 consecutive patients who had conventional RD repairs (i.e. external approach only). This yielded a primary success rate of 88.5% (46/52). Overall, vision improved in 26 cases (50%). For macula-off RDs, vision improved in 20 of 24 cases (83%) with 7 achieving 6/12 or better. Of the 6 failures, 5 had subsequent successful reattachment at the local VRU.

In all these cases pre-operative assessment and surgery were performed by a single consultant surgeon with strict adherence to exclusion criteria which included: limited fundal view due to media opacity, vitreous haemorrhage or miosed pupils, moderate to severe vitreoretinopathy, unidentifiable or very posterior breaks and giant tears. Our success rate is within the standard of 85–90% suggested by the authors and better than the 76% quoted by Laidlaw *et al*.[2] where conventional surgery alone was used. Another factor that will no doubt affect success rate is the number of procedures performed by a particular surgeon. We felt that even after patient selection there were still sufficient procedures done to keep the surgeon adept. If this was not the case, then we agree that all cases should be referred to a VRU. However, as the authors showed, this would have a significant effect on the workload in that VRU and there will be cost implications to both patient and doctor.

It is important to have a good primary reattachment rate as single surgery is associated with better visual outcome and reduced patient co-morbidity.[3] We advocate that all units that perform primary RD repairs constantly audit their own results to ensure that a good standard of care is being provided.

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Sir,

We read with great interest the article by Comer *et al*. 'Who should manage primary retinal detachments?'[1] There did indeed seem to be an important improvement in the success rate for primary retinal reattachment procedures when the majority of the surgery was performed by the 'specialist vitreoretinal unit (VRU)'.

However, what the authors are really saying is that patients with retinal detachments have better outcomes when managed by specialists. It does not follow that these specialists can only exist in a teaching hospital environment where a number of them can get together as a VRU, and to which patients from district general hospitals should be referred. A number of smaller units are now appointing properly trained VR surgeons who, if referred all VR cases from their colleagues in a DGH environment, will have a significant throughput of cases so that their expertise is maintained. The fact that there would frequently be fewer trainees at a DGH might arguably make it easier to obtain good results in comparison with a teaching hospital. One might argue that such superspecialisation in smaller units has a negative effect on training and on-call arrangements and is not cost-effective, but another audit comparing teaching hospital VRU versus specialist DGH success rates would be needed to prove the superiority of the centralised units suggested in this paper.

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