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Hydrophilic acrylic intraocular lens clouding: A clinicopathological review

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PURPOSE. *An analysis is made of a serious late complication (opacification) of different models of hydrophilic acrylic intraocular lenses (IOLs).*
METHODS. *Seven lenses were explanted from seven patients treated for cataracts with phacoemulsification and implantation of different types of hydrophilic acrylic IOLs (five SC60B-OUV from MDR, one Aquasense from OII, and one H60M Hydroview lens from Bausch & Lomb) who developed important vision impairment in the late postoperative period (1 to 3 years) due to lens opacification. The explanted lenses were subjected to exhaustive study involving photographic analysis, scanning electron microscopy, and energy dispersive X-ray spectroscopy.*
RESULTS. *Light and scanning electron microscopy revealed diffuse, variable-size granular deposits within the optic of the SC60B-OUV lens, and on the anterior and posterior optic surfaces of the H60M Hydroview lens, though without affecting the haptics in any of the models. Dispersive energy X-ray spectroscopy of the deposits revealed the presence mainly of calcium and phosphorus salts.*
CONCLUSIONS. *Hydrophilic acrylic IOL opacification is a serious late complication of unknown etiology. The condition is more frequent among diabetic patients, and the only management option is IOL explantation and replacement with a lens of some other material. More frequent and longer follow-up is required of those patients wearing lenses for which cases of opacification have been documented, particularly in the presence of predisposing factors (diabetes, uveitis). Caution is required with new lenses, avoiding their generalized use until they have successfully passed the test of time. (Eur J Ophthalmol 2007; 17: 588-94)*

KEY WORDS. *Hydrophilic acrylic intraocular lenses, Explantation, Opacification*

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INTRODUCTION

The introduction a few years ago of hydrophilic acrylic intraocular lenses (IOLs) constituted a major advance in the field of implantology. These lenses have become increasingly popular, thanks to the ease with which they can be folded and implanted in the capsular sac through a small incision; their good medium- and long-term tolerance attributable to the great biocompatibility of the material employed; and the ease with which YAG laser capsulotomy can be performed where required, without damaging the lens and thus minimizing certain complications. Different models have been developed, generally offering good short- and middle-term vision performance, though little is known of their potential long-term results and complications.

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In 1999, Chang et al (1) reported the first case of opacification of the optic of an SC60B-OUV (MDR) lens 7 months after implantation in a patient who developed important reduction and alteration of vision, without lens explantation. Many authors (2-5) have subsequently reported similar situations in the middle and late postoperative period, requiring explantation of this same lens model.

In 2000, Apple et al, Murray, and Werner et al (6-8) published various cases of Hydroview (Bausch & Lomb) lens opacification requiring explantation because of the vision problems caused. Since then, a number of authors have reported similar cases (9-12). On the other hand, in 2001, the explantation of Aquasense (Ophthalmic Innovations International, OII) acrylic IOLs was reported in different scientific congresses and meetings, and in 2002, Lee et al (13) published four cases of ACRL-C160 (Ophthalmed) lens opacification and explantation in diabetic patients between 10 and 20 months after IOL implantation. Finally, Kim et al (14) described a case of opacification and explantation of the same type of lens 4 months after cataract surgery in a patient with Behçet disease who had worsening of his uveitis, thereby contributing to cause greater and faster lens opacification.

The present study investigates the opacification of different models of hydrophilic acrylic IOLs in seven patients with cataract, based on photographic analysis, scanning electron microscopy, and energy dispersive X-ray spectroscopic assessment of the explanted lens.

METHODS

Between January 2001 and February 2003, we treated seven patients (five women and two men) who had undergone cataract surgery 1–3 years previously with phacoemulsification and implantation of a hydrophilic acrylic intraocular lens (IOL), without complications and presenting good vision recovery, but who in the late postoperative period experienced worsened vision due to opacification of the lens and/or posterior capsule. Six of these patients had been initially operated upon in other centers and were referred to us for cleaning of the lens and/or YAG laser capsulotomy.

In all seven patients slit lamp biomicroscopy showed the cause of vision impairment to be opacification with loss of transparency of the optic of the implanted lens, which appeared whitish-gray or brownish-black, similar in appearance to a nuclear cataract, and which impeded correct retroillumination. Consequently, following individualized photographic documentation of all seven cases, we decided to explant the opacified IOL and replace it with a lens made of a different material. In all cases the preoperative visual acuity was less than 0.3. All patients were over 70 years old (range 71–84), and prior to repeat surgery all were subjected to thorough anamnesis including systemic and local diseases, and present and past drug use. A detailed conventional preoperative study was also made, with full 24-hour blood and urine testing, special emphasis being placed on calcium, phosphorus, and ion concentrations, and intact parathyroid hormone (PTH) immunoassay.

Lens explantation was carried out under peribulbar local anesthesia through a corneal or scleral incision using a 3.2-mm scalpel blade with paracentesis. To this effect, a generous amount of viscoelastic material was introduced in the anterior chamber (to protect the endothelium) and capsular sac (to facilitate lens dissection and release from its adherences, particularly at the periphery where the latter are stronger). Progressive circular lens movements were applied with the help of a Sinsky hook or manipulators, and the freed lens was then extracted from the sac into the anterior chamber. Under viscoelastic protection and after enlarging the incision a little where necessary, the entire folded lens was extracted. This procedure proved possible in five cases, while in the remaining two patients the optic or haptics had to be sectioned using scissors. If the anterior capsular ring is very dense and fibrous, and the lens cannot be easily extracted, two small symmetrical incisions can be made to facilitate lens luxation into the anterior chamber. If opacification of the posterior capsule is moreover observed, it can be polished (as in three of our cases), followed where possible by implantation in the capsular sac of a new lens of some different material. However, in two of our patients the firm peripheral haptic adherences caused minor capsular disinsertion, while in one case vitreous was found in the anterior chamber, thus causing us to perform vitrectomy and implant a prepupillary iris support lens.

The following lenses were explanted: 5 Acryflex SC60B-OUV (Medical Development Research, MDR); one Aquasense (Ophthalmic Innovations International, OII); and one H60M Hydroview lens (Bausch & Lomb). All lenses were subjected to exhaustive study involving photographic analysis, scanning electron microscopy (XL 30 ESEM, Philips), and energy dispersive X-ray spectroscopy (EDX) using DX-4 software (Edax International) (the latter

two systems being located in the Faculty of Sciences, Valencia University, Spain).

RESULTS

The mean age of our seven patients was 74.4 years. Females predominated 5:2 (71.4% versus 28.6% males). All patients had been subjected to cataract surgery in a single eye. Two patients refused cataract surgery in the second eye, out of fear that the same problem would occur again; only when the opacified implant was replaced by a different lens and the outcome was seen to be good did these two patients agree to be treated in the other eye.

Visual acuity following explantation improved in all cases, with values of ≥0.5 in five patients. In only one individual (subjected to vitrectomy) was visual acuity equal to 0.3, due to the development of macular edema.

Lens extraction proved more laborious and difficult with the Acryflex SC60B-OUV (MDR) model, which is a monoblock lens with 28% hydrophilia, since in this lens the haptics were more strongly adhered to the periphery of the capsular sac. In two of the five cases it was necessary to section the optic or haptics in order to extract the opacified lens (Fig. 1), while another two cases presented zonular deinsertion, leading to capsular ring placement in one case, while the other developed vitrorrhagia requiring a vitrectomy with the implantation of a prepupillary Artisan-type (Worst) iris support lens. In the case of the Aquasense (OII) and H60M Hydroview (Bausch & Lomb) lenses, explantation was much easier, and was achieved in toto after folding the lens.

The opacified lens was replaced by polymethyl methacrylate (PMMA) lenses with an optic of <6 mm (812 C Pharmacia; and BV 359 Bausch Lomb) in four patients. One Artisan aphakia prepupillary lens (Ophtec) (5/8.5) was implanted with iris anchoring, while in the remaining three patients we implanted foldable lenses made of materials different from that of the explanted IOL (Acrysof, Alcon, in two cases and Hydroview BL in one patient). In six cases the new lens could be placed in the capsular sac.

The explanted SC60B-OUV (MDR) lenses showed uniform whitish opacification of the central portion of the optic, with preservation of the haptics and a 1 to 2 mm peripheral optic ring (Fig. 2). In the case of the Aquasense (OII) and H60M Hydroview (Bausch & Lomb) models, the entire optic appeared clouded, though not so the haptics (Fig. 3).

Scanning electron microscopic study of the explanted lenses showed the SC60B-OUV (MDR) implants to present multiple granular deposits of variable size and morphology within the lens optic and generally distributed in a line parallel to the curvatures and anterior and posterior surfaces of the lens, though preserving the optic periphery and haptics. In contrast, in the H60M Hydroview (Bausch & Lomb) lenses, the spherical or ovoid granular deposits covered the entire anterior and posterior surfaces of the lens, exhibiting an irregular cerebriform distribution but likewise preserving the haptics (Fig. 4).

Energy dispersive X-ray spectroscopy of the opacified granules showed the latter to be composed mainly of calcium and phosphorus, as can be seen from the spectroscopic peaks in Figure 5.

The biochemical laboratory tests and patient anamnesis showed five subjects (71.4%) to have diabetes and/or heart disease subjected to medical treatment, and with

Fig. 1 - Left: *Opacified SC60B-OUV (MDR) intraocular lens.* Middle: *Slit-lamp photography of the same eye with pupil dilatation.* Right: *The same opacified SC60B-OUV (MDR) intraocular lens explanted after sectioning the optic and a haptic.*

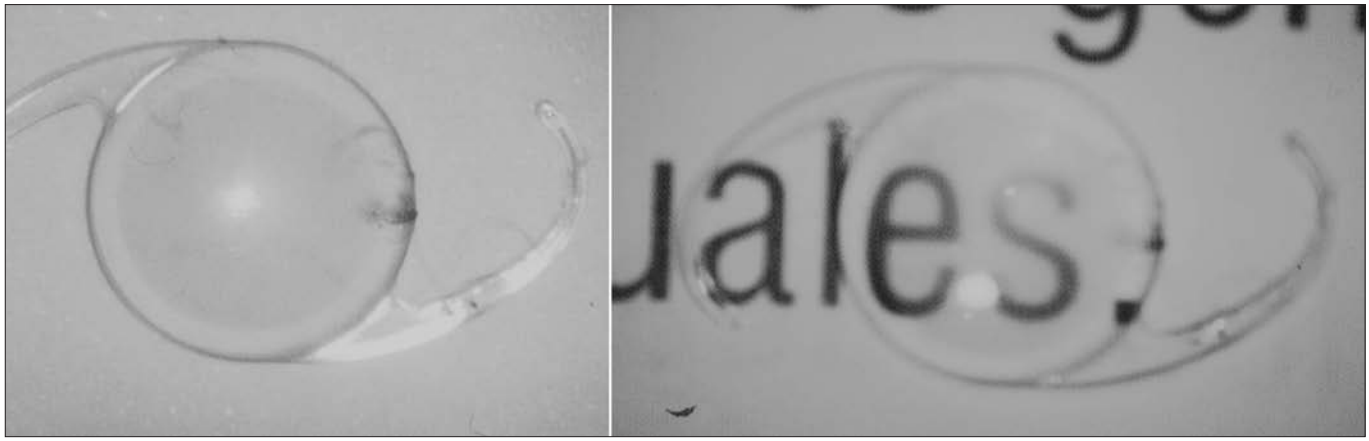


Fig. 2 - Left: *Opacified SC60B-OUV (MDR) intraocular lens explanted in toto. Note the central optic opacification with preservation of a 1- to 2-mm peripheral optic ring and the haptics.* Right: *The same opacified lens. Note the poor vision through the clouded optic.*

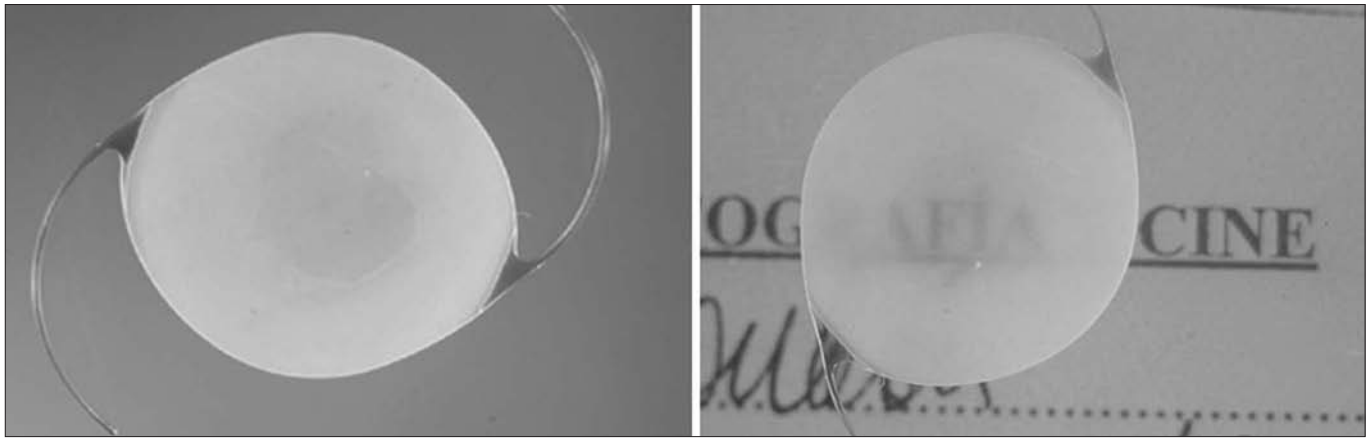


Fig. 3 - Left: *H60M Hydroview (Bausch & Lomb) model, the entire optic appeared clouded, though not so the haptics.* Right: *The same opacified lens. Note the poor vision through the clouded optic.*

high blood glucose and cholesterol levels. Three of the patients presented some form of diabetic retinopathy. Only two patients (28.6%) presented high blood and urine calcium concentrations, the rest of the determinations being normal, and both had had renal colic in the past, associated with the presence of calcium oxalate stones.

DISCUSSION

To date, the SC60B-OUV (MDR) model has generated the greatest incidence of opacification and explantation, and the manufacturing company reported that of more than 74,000 lenses implanted up until early 2000, only 0.74% were associated with this late complication. As a result, in

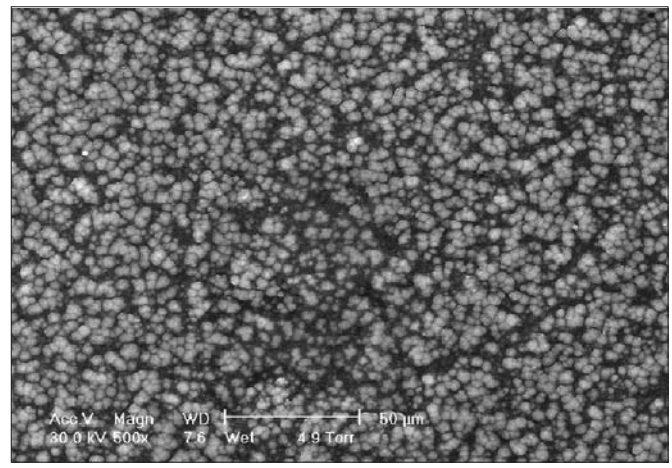
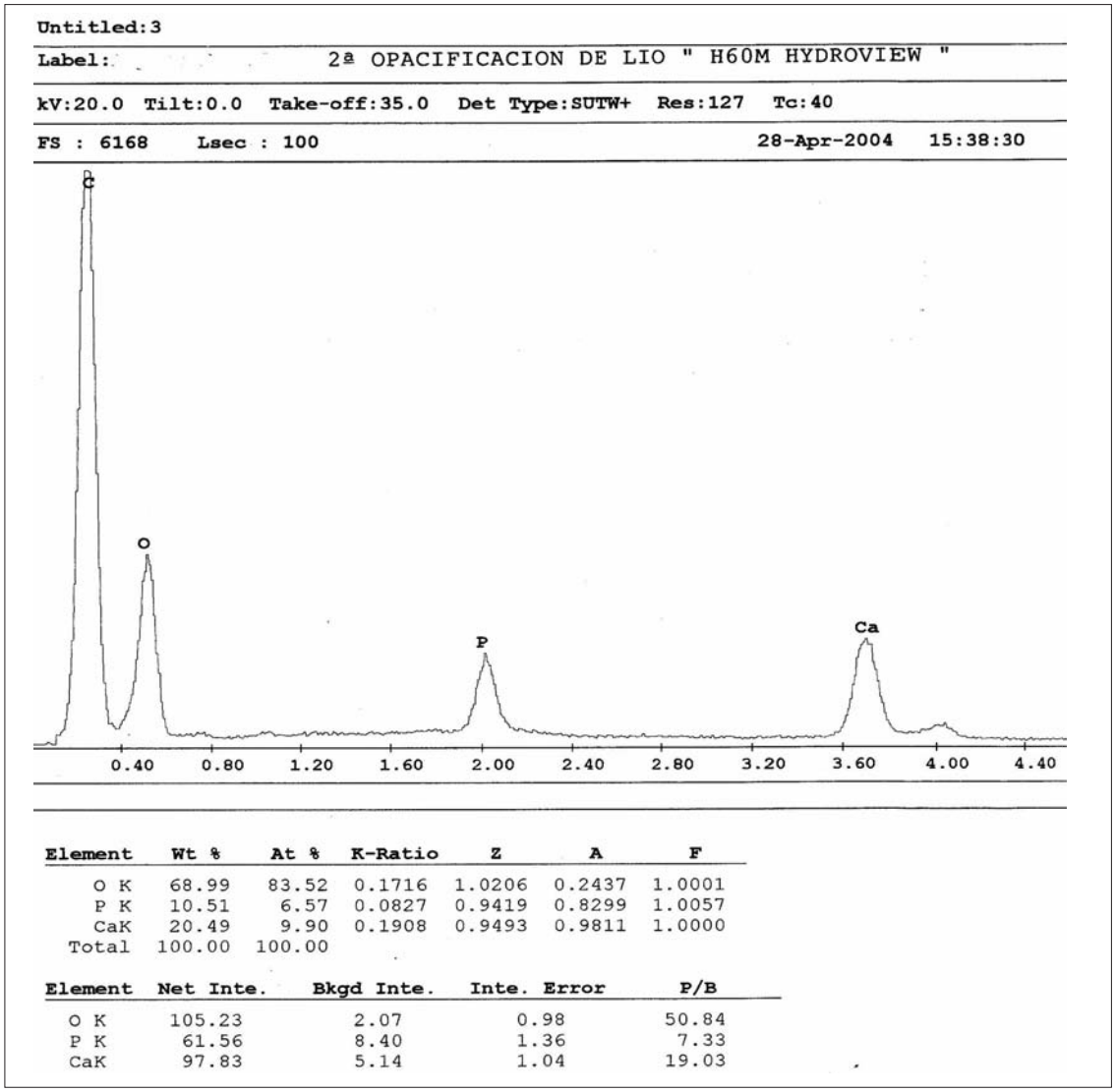


Fig. 4 - *Scanning electron microscopy of an explanted H60M Hydroview lens exhibiting granular deposits in an irregular cerebriform distribution.*



Element	Wt %	At %	K-Ratio	Z	A	F
O K	68.99	83.52	0.1716	1.0206	0.2437	1.0001
P K	10.51	6.57	0.0827	0.9419	0.8299	1.0057
CaK	20.49	9.90	0.1908	0.9493	0.9811	1.0000
Total	100.00	100.00				

Element	Net Inte.	Bkgd Inte.	Inte. Error	P/B
O K	105.23	2.07	0.98	50.84
P K	61.56	8.40	1.36	7.33
CaK	97.83	5.14	1.04	19.03

Fig. 5 - *Spectroscopic analysis of the explanted H60M Hydroview (Bausch & Lomb) intraocular lens, showing the calcium and phosphorus peaks.*

June of that same year MDR reported this circumstance in writing to all users, which the company attributed not to the actual lens material but to the polymer used (supplied by Vista Optics, in the United Kingdom), and informed that the distribution and export of this lens model would cease. On June 19, the Spanish Health Ministry notified cessation of the implantation in this country of the SC60B-0UV (Acryflex) and SC600-2 (Cirrus) models produced by MDR, which were imported to Spain through four distributors. Since then many further cases have been reported of lens clouding and explantation of these models. As a result, the initially estimated incidence of 0.74% has been greatly increased by the subsequent publication of new cases (2-5, 15, 16).

In its latest report, Bausch & Lomb, the manufacturer of the H60M Hydroview lens, indicated that out of 790,000 lenses sold, only 394 cases of clouding had been documented, corresponding to an incidence of a little under 0.05%. The company attributed this incidence to the introduction in 1997 of a new Surefold lens packaging system involving the fitting of a solid silicone washer ring. Following heat sterilization, the latter was released, and after mixing with free fatty acids the resulting chemical reaction was seen to form a membrane on the lens surface that attracted calcium from the aqueous humor, generating deposits and thus inducing lens opacification, as described by Trivedi et al (17). At present, silicone has been suppressed from the product, and the incidence of new cases has been minimized as a result.

Although the pathogenesis of hydrophilic acrylic lens

clouding is not known (18), the phenomenon is believed to be multifactorial, and a number of authors such as Frohn et al (2) and Macky et al (19) consider opacification to be due to premature aging of the ultraviolet blocking agents, clouding therefore implying a change in the actual SC60B-0UV lens material.

Other authors, such as Werner et al (8) and Lee et al (13), consider that systemic metabolic disorders also exert an influence, since lens clouding is more common in diabetics and in patients with heart disease and hypertension, those subjected to systemic treatment with anticoagulants, diuretics, and antihypertensive agents. In effect, clouding is much more frequent and severe in diabetics, as we have been able to observe in our own series (five diabetics out of seven subjects [71.4%], of whom three presented some degree of retinopathy). On the other hand, Pandey et al (20) published the first case of total bilateral opacification of two SC60B-0UV lenses in which the optic periphery also appeared clouded, along with the haptics, in a patient with a 20-year history of type 2 diabetes mellitus and proliferative diabetic retinopathy with cystoid macular edema and bilateral diffuse maculopathy.

In coincidence with our own observations, lens clouding and explantation generally occurs 1–3 years after implantation, though there are also much earlier cases, such as that published by Kim et al (14) in a patient with Behçet disease. Four months after implantation of an ACRL-C160 (Ophthalmed) lens and exacerbation of his uveitis, the patient had lens clouding requiring explantation. Likewise, in the case reported by Pandey et al (20), involving a diabetic patient with diabetic retinopathy, opacification occurred less than 1 year after cataract surgery. These observations suggest that an important factor underlying lens clouding is represented by both the metabolic imbalances found in diabetic patients and the increased fragility of the blood–aqueous barrier, with an increased inflammatory response following surgery in such individuals, though there have also been reports of lens clouding in healthy patients without systemic disorders. Consequently, no patient wearing hydrophilic acrylic intraocular lenses is immune to this rare complication. The anterior findings contrast with the also described “snowflake” or crystalline degeneration of PMMA IOLs, which occurs long-term postoperatively (often a decade or more), and is attributed to manufacturing problems (21).

The results of our scanning electron microscopic and X-ray spectroscopic analyses coincide with those published in the literature (22-24), and point to the accumulation of granular deposits composed mainly of calcium, with a quite uniform distribution within the SC60B-OUV (MDR) lens optic and on the surfaces of the other lens models investigated.

All attempts to eliminate the deposits causing lens opacification by means of the YAG laser have been unsuccessful; use of the latter should therefore be avoided, and the only valid management option for restoring good patient vision consists of explantation and replacement with a different lens. This procedure may prove difficult in cases where a prior YAG laser capsulotomy has been performed.

The opacification of hydrophilic acrylic IOLs is a serious complication of unknown etiology, with the only effective treatment being lens explantation and replacement, preferably involving a lens of some different material.

Since the incidence of lens clouding is much greater among diabetics, we consider that such patients should be subjected to more frequent and prolonged follow-up, particularly if they are wearing lenses for which opacification has been documented in the literature. On the other hand, caution is required with new lenses, avoiding their generalized use until they have successfully passed the test of time. Implantation should moreover be avoided in young patients with known risk factors (diabetes associated with retinopathy, uveitis), since these eyes are more prone to blood–aqueous barrier rupture following surgery, with increased postoperative inflammation. Indeed, total bilateral clouding has already been documented in a diabetic patient (20).

In the event of any important anomaly developing in relation to an implanted IOL, the manufacturer and distributor should be promptly notified, particularly if problems are observed with new models that have not been subjected to medium- and long-term evaluation.

We consider that although the incidence of opacification is not very high, the patient should be warned in advance of the remote possibility of lens clouding in time. This aspect should also be addressed in the corresponding patient consent document.

Proprietary interest: None.

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