INTRAOCULAR LENS EXCHANGE FOR LATE-ONSET OPACIFICATION

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SUMMARY

Purpose: To report on the clinical, light microscopic and spectroscopic analyses of Hydroview intraocular lenses (IOLs) explanted for late postoperative IOL opacification.

Material and Methods: Retrospective study of all cases with secondary lens implantation performed at the University Hospital of Antwerp during a period of one year (2002-2003) for postoperative opacification of Hydroview IOLs. Further analyses on some of the explanted IOLs included gross and light microscopic evaluation and RAMAN spectroscopy.

Results: Lens exchange for late-onset IOL opacification was needed in seven eyes of six patients. IOL opacification became apparent between 15 and 25 months after uneventful phacoemulsification and lens implantation. Visual acuity varied from < 0.05 to 0.6 before explantation. In almost all cases postoperative visual acuity improved to the pre-opacification level. Light microscopic and spectroscopic analyses showed that the opacification was mainly located in the anterior portion of the IOL optic as a layer of irregular granular deposits composed of calcium phosphate.

Conclusion: Late postoperative opacification of Hydroview IOLs may cause severe visual impairment, requiring explantation. Calcium phosphate is involved in the formation of these opacifications. Reporting on this type of complications is mandatory according to the Belgian and European directives for medical devices.

RÉSUMÉ

But: Etude clinique, microscopique et spectroscopique de lentilles intraoculaires ''Hydroview'' explantées pour opacification post-opératoire tardive.

Matériel et méthodes: Etude rétrospective de tous les cas d'implantation secondaire effectués à l'Hôpital Universitaire d'Anvers pendant 1 an (2002-2003), suite à l'opacification post-opératoire de lentilles ''Hydroview''. Sur certaines lentilles explantées des examens supplémentaires ont été pratiqués, notamment examen macroscopique, examen microscopique et spectroscopie selon la technique de RAMAN.

Résultats: Un échange de lentille a été nécessaire dans sept yeux de six patients. L'opacification est apparue de 15 à 25 mois après une phaco-émulsification par ailleurs sans complications. L'acuité visuelle variait de < 0.05 à 0.6 avant l'échange. Dans la plupart des cas, l'acuité visuelle a récupéré le niveau pré-opacification. L'analyse microscopique et spectroscopique a montré que les opacifications étaient principalement localisées dans la partie antérieure de l'optique sous forme d'une couche granulée irrégulière de phosphate de calcium.

Conclusion: L'opacification tardive de l'implant Hydroview cause une baisse sévère de l'acuité visuelle, nécessitant une explantation. Les opacifications sont formées de phosphate de calcium. D'après les législations belges et européennes sur les dispositifs médicaux, il est obligatoire de rapporter ce genre de complications aux autorités compétentes.

SAMENVATTING

Doel: Beschrijving van de klinische, licht-microscopische en spectroscopische analyse van Hydroview intraoculaire lenzen (IOL), die geëxplanteerd werden omwille van laattijdige postoperatieve IOL opacificatie.

Materiaal en methoden: Retrospectieve studie van alle gevallen van secundaire lensimplantatie, uitgevoerd in het Universitair Ziekenhuis Antwerpen gedurende de periode van één jaar (2002-2003), voor postoperatieve opacificatie van Hydroview intraoculaire lenzen. Verdere analyse van een aantal geëxplanteerde lenzen omvatte macroscopische en lichtmicroscopische analyse enerzijds en RAMAN spectroscopie anderzijds.

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Resultaten: Secundaire lensimplantatie naar aanleiding van laattijdige IOL opacificatie was noodzakelijk in zeven ogen van zes patiënten. De IOL opacificatie werd zichtbaar tussen 15 en 25 maanden na de initiële phacoemulsificatie en lensimplantatie. De visus voor explantatie varieerde tussen < 0,05 en 0,6. Na de ingreep verbeterde de visus en bereikte in de meeste gevallen het niveau van voor de opacificatie. De licht-microscopische en spectroscopische analyses toonden aan dat de opacificatie voornamelijk gelocaliseerd was in het voorste gedeelte van de IOL optiek. De opacificatie deed zich voor onder de vorm van een onregelmatige korrelige neerslag van calciumfosfaat.
Conclusie: Laattijdige postoperatieve opacificatie van Hydroview IOLs kan ernstig zichtverlies veroorzaken waardoor explantatie noodzakelijk is. Calciumfosfaat is betrokken bij de vorming van deze opacificaties. Het rapporteren van dit type complicatie is niet alleen noodzakelijk maar zelfs verplicht volgens de Belgische en Europese richtlijnen voor medische hulpmiddelen.

KEY WORDS

Hydroview IOL, IOL opacification, IOL exchange

MOTS-CLÉS

Lentilles intraoculaires Hydroview, opacification tardive, explantation

INTRODUCTION

Cataract surgery consisting in the removal of the natural lens through a small incision (3 mm or less) and consecutively the implantation of a foldable intraocular lens (IOL), is the most successful surgical procedure performed worldwide in medicine. The low complication rate is the result of the continuous progress booked as well in the field of the surgical technique as in the field of the biomaterials used for the manufacturing of the intraocular lens. This ongoing search for improvement has encountered lately some drawbacks, as some patients implanted with Hydroview IOLs experienced late-onset visual impairment. This decrease in visual acuity was not due to posterior capsule opacification as it is regularly encountered after cataract surgery, but was due to progressive opacification of the intraocular lens.

While presenting our results of intraocular lens exchange for progressive IOL opacification, we would also like to stress the importance of recording and reporting complications related to the use of these medical devices.

MATERIALS AND METHODS

We collected retrospectively all cases of IOL exchanges for late-onset postoperative Hydroview IOL opacification performed at the University Hospital of Antwerp between October 2002 and December 2003. Seven eyes out of six patients needed IOL exchange for this indication.

In all patients age, gender, medical history and ophthalmic history were collected. Since all patients were referred by peripheral ophthalmologists, information about the initial IOL implantation, IOL serial number and preoperative visual acuity was obtained after personal contact. Information about the IOL exchange itself and more specifically about the surgical procedure and complications, were reviewed from our own files. Visual acuity before cataract surgery, during IOL opacification and after IOL exchange was compared. Two explanted Hydroview IOLs were analysed by light microscopy and RAMAN spectroscopy.

RESULTS

Patient history and Hydroview IOL implantation

The mean age of the six patients - 2 men and 4 women - was 72 years (between 68 and 80 years). In their medical history we found cardiovascular pathology in all patients. One patient had cardiovascular surgery in the past while the others were treated medically. Three patients suffered from diabetes type 2. One patient had COPD treated by corticosteroids. One patient suffered from Kugelberg-Wiellander disease, a rare neuromuscular disorder.
In their ophthalmic history we found a diabetic retinopathy treated by panphotocoagulation in two patients. One patient was highly myopic and one patient was treated topically for chronic open angle glaucoma. All patients underwent cataract surgery by phacoemulsification with Hydroview IOL implantation. These procedures were performed by three different surgeons in three different settings between October 2000 and February 2002. Phacoemulsification and intracapsular implantation of a Hydroview IOL was uneventful in most cases. However, one patient presented a posterior capsule rupture still allowing a lens-in-the-bag implantation and another required sulcus placement of the IOL. Mean visual acuity improved from 0.4 (0.2 to 0.55) preoperatively to 0.8 (0.4 to 1.0) postoperatively. There were no significant postoperative complications. Two patients presented corneal oedema, which needed prolonged postoperative treatment. YAG laser capsulotomy was performed in one patient for posterior capsule opacification.

Hydroview IOL opacification

The patients consulted their ophthalmologists for visual impairment 15 to 25 months postoperatively (average 21 months). The right eye was affected in 5 cases, the left eye in 2 cases. One patient had both eyes affected. All patients complained of a rapid progression in visual impairment without other ocular symptoms. Visual acuity decreased dramatically to values between 0.6 and < 0.05. On slit lamp examination the IOL opacification could be classified in two groups: granular deposits on the IOL sur-

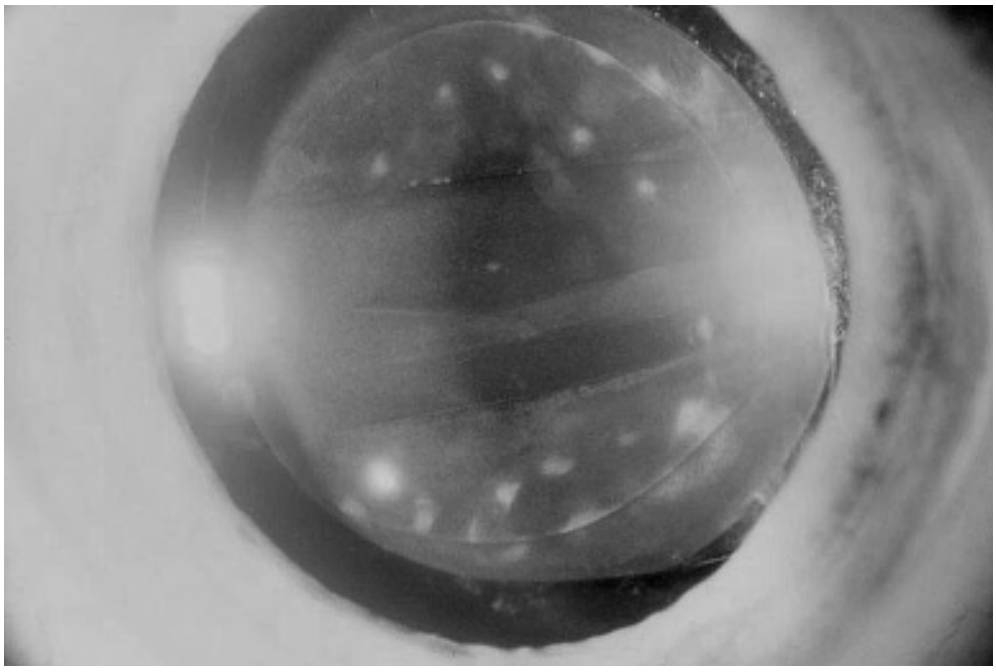

Fig 1. Hydroview IOL opacification: granular deposit type.

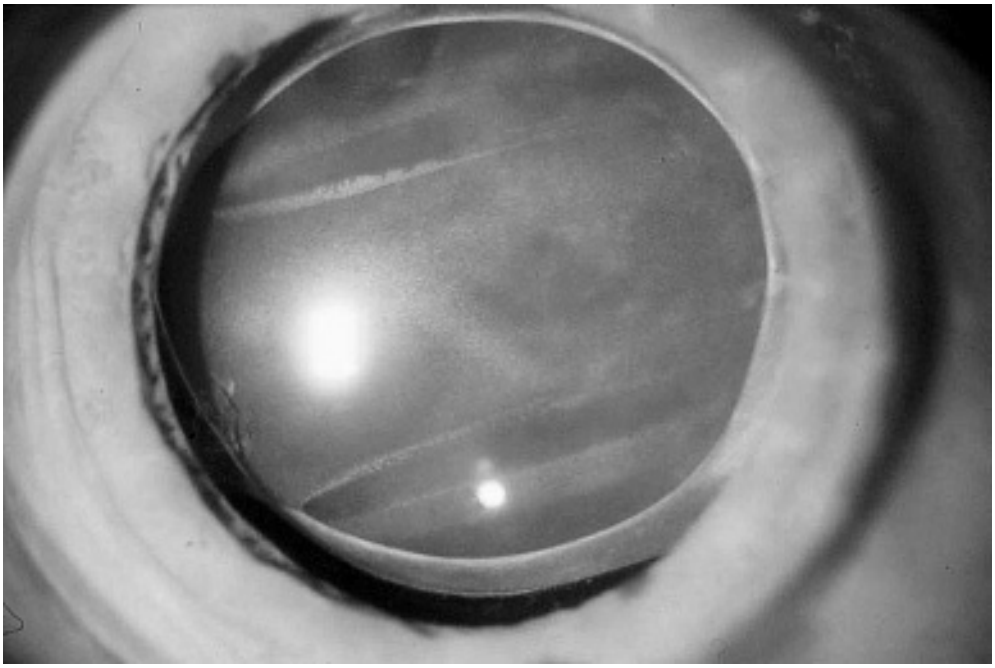

Fig 2. Hydroview IOL opacification: opaque type.

face (fig. 1) or a completely white opaque IOL (fig. 2). No inflammatory reaction was detected in the affected eyes.

IOL exchange

All IOL exchanges were performed at the University Hospital of Antwerp by one surgeon between October 2002 and December 2003, respectively 25.8 months (between 22 and 32 months) after the initial surgery. Because of the long interval between the initial surgery and the explantation, it was not always easy to free the IOL from the intracapsular lens epithelial cell (LEC) proliferations.

In most cases an extensive anterior capsular fibrosis was present. In two patients zonular lysis with partial capsular dehiscence occurred during surgery. In all cases the IOL was removed completely, either in one, two or three pieces. A capsular tension ring was introduced in the capsular bag in three eyes and a posterior capsulorhexis was performed twice in the same surgical procedure. The patient who had a YAG laser capsulotomy in the past also needed anterior vitrectomy. The opacified IOL was replaced by an Acrysof SA30AL IOL in all cases. Lens-in-the-bag positioning was possible in five eyes. In two eyes the lens was positioned in the sulcus and in one of them also fixated to the sclera at one-point. Because of a progressive tilting, we exchanged the latter by an iris-fixated IOL 2 months later. Best-corrected visual acuity postoperatively increased to 0.75 (0.4 to 1.0) and reached in six of the seven eyes the pre-opacification level (fig. 3). One patient lost 0.25 Snellen lines compared to the immediate visual acuity after primary cataract surgery.

Analysis on the explanted IOLs

In order to evaluate the exact structure and composition of the IOL opacification, two explanted opacified Hydroview IOLs were subjected to analysis by light microscopy and RAMAN spectroscopy. At low magnification (10x) a cloudy area could be demonstrated in the anterior part of the IOL optic. By increasing the magnification (x50) this area appeared as a layer of irregular granular deposits, composed of multiple fine translucent spherical-ovoid granules (microspheres) covering the anterior surface of the IOL optic. No changes were found

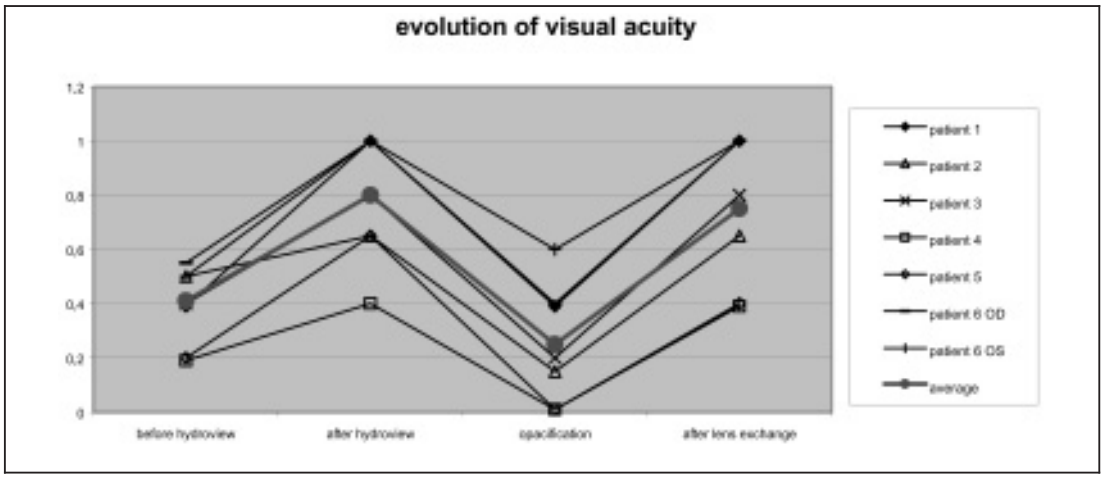

Fig 3. Evolution of visual acuity.

in the deeper part of the lens or at the level of the haptics.

Further analysis was performed by RAMAN spectroscopy. First, a reference spectrum was recorded by analyzing a clear area of the Hydroview IOL optic (fig. 4). On this spectrum major bands were observed at 603, 970, 1448 and 1728 cm^{-1}. When focused on an opacified area of the Hydroview IOL optic (fig. 5), an additional and intense peak could be observed around 962 cm^{-1}. After highlighting this band by mathematically subtracting the reference spectrum from the spectrum of the opacified area, it was compared with spectra from the RAMAN library. The spectrum that matched best the profile of the opacified material was calcium phosphate (fig. 6). This compound is known to be the basic constituent of hydroxyapatite. However, we did not detect the weak OH group of the hydroxyapatite at 3600 cm^{-1}.

DISCUSSION

Late postoperative Hydroview IOL opacification was first reported in 1998 (8). A few hundred cases have been reported since.

Cardiovascular pathology and diabetes were often found in the medical history of patients presenting IOL opacification. However, both comorbidities were also commonly found in patients without IOL opacification after Hydroview IOL implantation. Hydroview IOL opacification has also been reported in patients without medical history (3, 4, 6, 8, 9). The initial implantation of the Hydroview IOL was uneventful in almost all reported cases (8). In our series, posterior capsule rupture was reported in one patient.

Hydroview IOL opacification was not observed earlier than 4 months postoperatively (8, 9). and was observed at the latest at 29 months postoperatively (1). In our series, IOL opacification became obvious between 15 and 25 months after initial surgery. All patients complained of a sudden decrease in visual acuity without other symptoms. It has been reported by different authors that visual acuity dropped below 0.05 Snellen lines in most of the cases (3, 4, 8, 9). Decrease in contrast sensitivity was studied by Fernando (2). All papers described the IOL opacification as whitish-grey or brown granular deposits covering the IOL surface partially or completely. Intraocular inflammation was not found in association with IOL opacification (1, 2, 6, 7, 9).

IOL exchange is the only option to cure this condition. Nd:YAG laser was proposed to clean the IOL (2, 6, 7, 9). This technique remained unsuccessful and made the IOL explantation even more difficult. Because of the late-onset of the opacification, proliferative tissue was abundantly present at the capsular equator as well as on the anterior capsule. Meticulous dissection of the IOL from the capsular bag with viscoelastic material is mandatory in order to free the IOL from the capsular bag. Cutting of the hap-

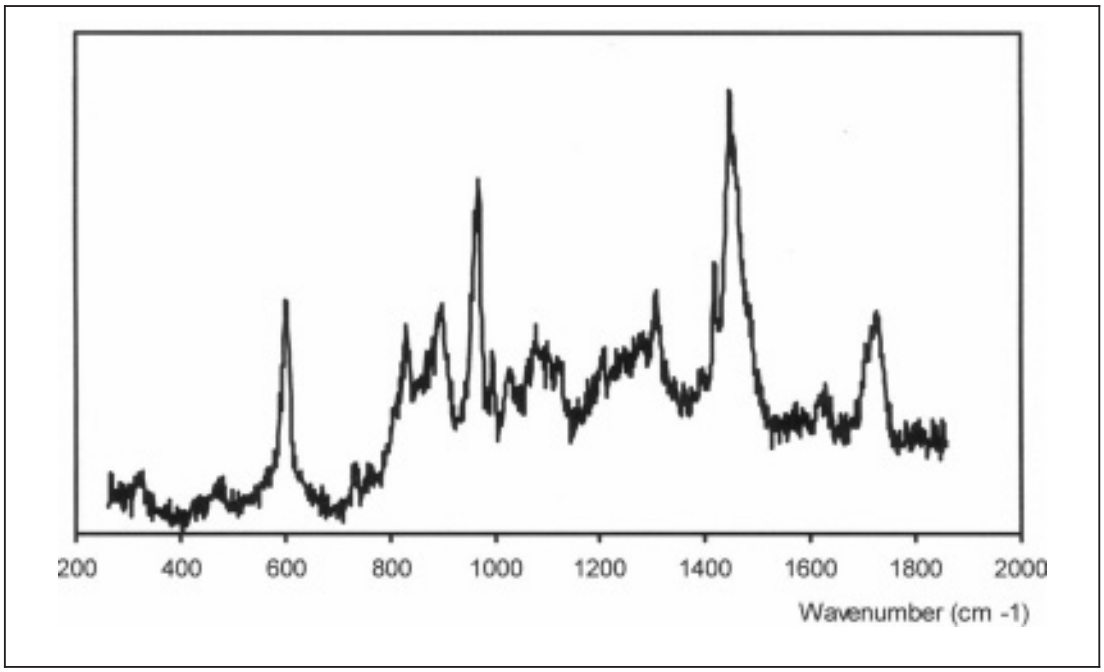

Fig 4. Spectrum of a transparent Hydroview IOL.

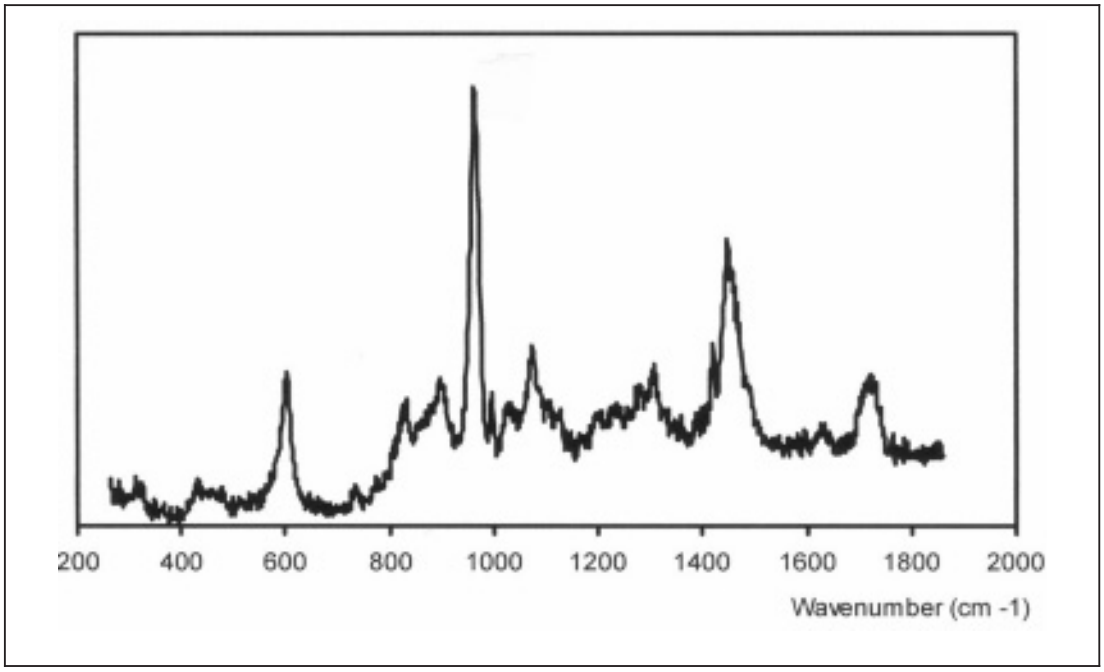

Fig 5. Spectrum of an opacified Hydroview IOL.

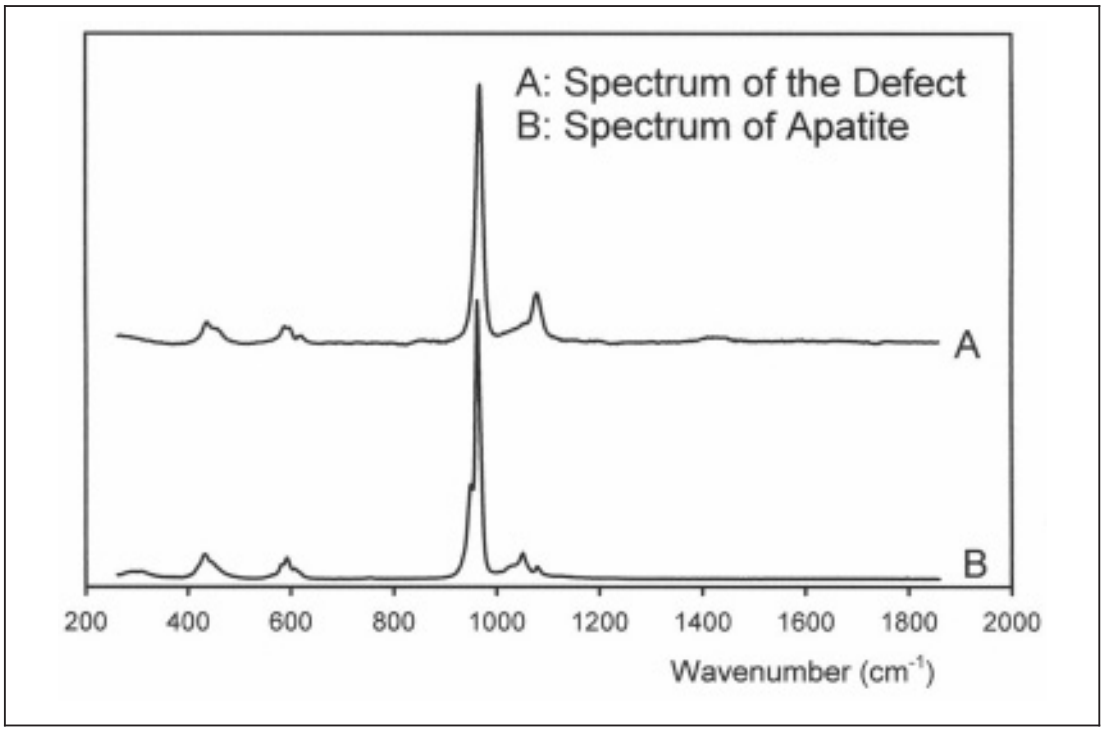

Fig 6. The spectrum of the opacification defect matched best with the calcium phosphate spectrum of hydroxyapatite.

tics has been proposed to facilitate IOL removal. (9) Frequent peroperative complications reported in the literature were posterior capsular rupture and zonular dehiscence (9). In our series two patients presented zonular dehiscence. Lens-in-the-bag implantation has been reported as still possible in most of the cases (3, 9). Sulcus placement, anterior chamber or scleral fixation were the other options. In our series, one patient needed a one-stitch scleral fixation because of zonular dehiscence of 180°.

After IOL exchange, visual acuity improved up to the pre-opacification level in most but not all cases (3, 5, 9). In our series, one patient lost 0.25 Snellen lines, which was partially related to a progression of his diabetic retinopathy.

Gross and light microscopic evaluation of the explanted Hydroview IOLs showed the same features as described in the literature: a layer of irregular granular deposits was present at the anterior IOL surface but not at the level of the haptics (2, 6, 7). In some cases both anterior and posterior surfaces were almost completely covered, whereas in other cases some intermediate clear areas were observed. Calcium was detected on the IOL surface by staining with alizarin red and using the von Kossa method (1, 6, 7). Transmission electron microscopy (TEM) showed electron dense crystalline deposits on the IOL surfaces (5). Some authors reported alterations within the IOL optic (1, 3, 4). On scanning electron microscopy (SEM), the opacification had a “cerebriform” appearance (2, 5). Different authors used energy dispersive X-ray analysis (EDXA) and RAMAN spectroscopy to demonstrate the presence of calcium and phosphate (2, 5, 6, 7). Silicon was also found in most of the deposits by Dorey et al (1).

Silicon derived from the silicon gasket in the Surefold packaging system may come loose from the packaging onto the optic of the IOL and may act as a nidus for calcium deposition in the presence of fatty acids or all metabolic diseases releasing these moleculaes (1, 6).

The manufacturer of the lenses has done considerable research to find out the cause of this complication. Having analyzed all available data,

including medical history, processing, surgical settings and techniques, environmental factors and packaging, their search pointed in the direction of the packaging. Having changed the packaging in April 2001, no new reports of postoperative Hydroview IOL opacification have been reported since.

We would also like to stress the importance of reporting this type of complications. This is mandatory according to the Belgian (K.B. 18/03/1999, Art. 11) and European (93/42 and 90/385) directives concerning medical devices. A vigilance report of each incident has to be sent to the Federal Public Service for Health, Food Chain Safety and Environment, Department Medical Devices. More information about this procedure can be obtained at the Department of Medical Devices (http:www.health.fgov.be).

CONCLUSION

Late postoperative Hydroview IOL opacification causes a rapid and dramatical loss of visual acuity. The opacification was located in the anterior portion of the IOL optic. RAMAN spectroscopy confirmed the calcium phosphate composition of the deposits. IOL exchange is the only treatment for this condition as soon as visual acuity has reached uncomfortable levels. Although very successful in most cases, these lens exchange procedures are often very challenging because of the high rate of LEC proliferation within the capsular bag. Reporting on this type of complications is mandatory. After changing the packaging in 2001, no new reports on Hydroview IOL opacification have been published.

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