IOL's Opacification: A Complex Analysis Based on the Clinical Aspects, Biomaterials Used and Surface Characterization of Explanted IOL's

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IOL opacification is a growing issue reported lately in the speciality literature. [1-5] This article follows a series of retrospective cases regarding hydrophobic IOLs that were explanted from three different patients. The explants were examined using AFM and SEM (with EDS), in order to find more details about the surface morphology and the composition of the deposits. The results indicate that they are composed mainly of calcium and phosphate. The authors suggest that ocular comorbidity and other systemic factors are contributing to this complication.

Keywords: IOL opacification, explanted IOL, surface deposits

An intraocular lens implant (IOL) is a synthetic, artificial lens placed inside the eye that replaces the focusing power of a natural lens that is surgically removed, usually as part of cataract surgery. There are two types of IOLs: pseudophakic (IOL) and phakic intraocular lens (PIOL). The pseudophakic IOL is the most common type, and are implanted during cataract surgery, after the cloudy crystalline lens (cataract) has been removed. The phakic intraocular lens (PIOL) is a lens that is placed over the existing natural lens, and is used in refractive surgery to change the eye optical power as a treatment for myopia IOLs usually consist of a small plastic lens with plastic side struts, called haptics, to hold the lens in place within the capsular bag inside the eye.

IOLs were traditionally made of an inflexible material (PMMA), although this has largely been superseded by the use of flexible materials. Most IOLs fitted today are fixed monofocal lenses matched to distance vision. However, other types are available, such as multifocal IOLs that provide the patient with multiple-focused vision at far and reading distance, and adaptive IOLs, which provide the patient with limited visual accommodation.

The ideal IOL should offer easiness of implantation, lack of intraoperative complications, good and long-lasting vision, and refractive stability.

Recently, a tendency has developed preferring foldable IOLs and especially those suitable for micro incision cataract surgery (MICS), i.e. those IOLs that can be implanted through sub-2 mm incision. These lenses are usually hydrophilic acrylic single-piece IOLs. IOL materials are defined hydrophobic or hydrophilic according to the angle a drop of water makes with respect to the material surface. The more acute this angle is, the more hydrophilic the material is defined. Hydrophilic IOLs are very popular in Europe because of the easy handling, the sub-2-mm implantation, the low risk for capsular bag damage during implantation, and the improving results with posterior capsular opacification (PCO).

The several types of IOLs currently available can be differentiated in several ways, the most important of which are shown in the table 1.

Post operative opacification of intraocular lenses (IOLs) has been reported in a variety of clinical settings and with various IOL types and materials available [1-4,6,7].

Depending on the underlying process, IOLs can become opacified or discolored at any time during or after surgery. Intraoperative and postoperative medications, such as topical steroids and beta-blockers, and those containing phosphorous compounds, such as some glaucoma medications, have been hypothesized to promote this phenomenon [7]. IOL opacification is a major cause of

Destination Capsular bag, ciliary sulcus, scleral fixation, iris fixation, angle supported

Overall design 3 piece/1 piece Overall length 10-13 mm

Optics material Rigid (PMMA), flexible (silicone), foldable (hydrophobic acrylic

hydrophilic acrylic), Collamer

Refraction index 1.42–1.55

Optics shape shape Biconvex, plano-convex, meniscus

Optics diameter 5–7 mm

Optics design Spherical, aspheric, toric multifocal, multifocal toric

Optics color Transparent, tinted

Haptics properties properties 3 piece/1 piece (PMMA, PVDF, polyamide, 2, 3, 4, 6 haptics)

Type of Injectable, not injectable

implantation

Type of packaging Pre-loaded, not pre-loaded

Table 1 CLASSIFICATION OF IOLs

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explantation due to symptoms such as glare and low visual acuity.

The purpose of our paper was to report a detailed analysis of a series of cases of IOL opacification, based on the clinical observations and surface analysis of the explanted IOLs.

Experimental part

We collected retrospectively all cases of IOL exchanges for late-onset postoperative. All IOLs were explanted due to significant visual impairment. In each case, the lens has been explanted due to deposition of crystalline material on its optical surfaces associated with a decrease in visual acuity (VA) and glare in the late postoperative period.

By gross evaluation and light microscopy, the presence of the deposits on their optical surfaces was noted to cause different degrees of IOL haze/opacification directly proportional to the amount of deposits on the IOL. A layer of irregular granular deposits, composed of multiple, fine, translucent spherical-ovoid granules covered the surfaces of the IOLs. In generally, the deposits occurred on both anterior and posterior IOL optic surfaces, and also in the thickness of the lens [8]. In our cases, both surfaces were almost completely covered by a fine confluent granular layer, with some intervening clear areas in between.

After initial primary gross and macroscopic examination, the lenses were analyzed using scanning electron microscopy (SEM) equipped with an energy dispersive x-ray spectroscopy detector (EDS) and atomic force microscopy (AFM) in order to find more details about the surface morphology and the composition and distribution of the deposits causing opacification of their optic components. Surface analysis of the explanted lenses was performed in the laboratory of Materials Science and Engineering Faculty, University POLITEHNICA of Bucharest. The equipment used for investigation was a scanning electron microscope type Phillips XL-30 ESEM and an atomic force microscope type Veeco Multi Mode VS-AM.

Patient history and other details about the clinical cases are described below. First patient was a 72-year-old male who was submitted for examination after he underwent phacoemulsification in another medical center with uneventful implantation of a hydrophilic acrylic lens in the right eye on September 2011 and in the left eye on October 2011. The patient had a medical history of hypertension and diabetes. From the anamnesis resulted that there were no intraoperative or immediate postoperative complications. His fundus exam was normal on the day of presentation. He presented 30 months after the surgery in the left eye with a decrease in this eye's BCVA from Snellen 1 on the thirtieth postoperative day evaluation to Snellen 0.2. BCVA in the right eye was preserved. Ocular examination only revealed haziness on the left IOL's surfaces. The IOL in the left eye was explanted 41 months postoperatively and a hydrophobic acrylic type MA 60 AC (Alcon Inc.) IOL was implanted in the sulcus. This eye's final BCVA was Snellen 0.7.

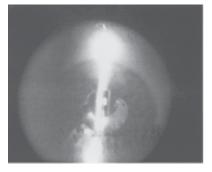
The second patient was a 59-year-old female with severe non-proliferative diabetic and hypertensive retinopathy who was submitted during September 2010 in a fellow medical facility and underwent phacoemulsification with uneventful implantation of a posterior chamber IOL in the right eye. From the medical records resulted that there were no intraoperative complications. At the moment of the surgery, the patient had hard exudates in the macula and few microaneurysms in the right eye. In the left eye, she had mild nuclear and cortical sclerosis. Pan-retinal photocoagulation and an intravitreal injection of triamcinolone acetonide and Avastin were done in both eyes three and two years prior to cataract surgery. One month after phacoemulsification, she presented at our facility with hard exudates in the macula and clinically significant macular edema. She was submitted for triamcinolone acetonide and Avastin and grid photocoagulation one month later. Her uncorrected vision after the laser was Snellen 0.4. Twenty-six months after surgery, her uncorrected visual acuity in the right eye was Snellen 0.2. She had no macular edema or macular exudates. Thirty months postoperatively she presented with an uncorrected vision on the right eye of Snellen 0.1. On biomicroscopy IOL and opacification was noted. The IOL was explanted two months later. A posterior vitrectomy was also performed. A hydrophobic acrylic IOL was implanted in the ciliary sulcus. Two months after IOL exchange, the BCVA in the right eye was Snellen 0.4.

The last patient was a 62-year-old woman with a hydrophobic acrylic IOL and without a prior history (except for the cataract surgery) presented 26 months postoperatively with a rhegmatogenous retinal detachment. She underwent 25-gauge pars plana vitrectomy using perfluoro-*n*-octane (PFO), air-fluid exchange and C3F8 gas tamponade. One week after surgery, a non-buoyant fluid bubble thought to be PFO was noted to fill 2 to 5 % of the postremal chamber. Posterior 25-gauge pars plana vitrectomy was performed on postoperative week 4 to remove the retained PFO. Anterior segment examination at one month postoperative revealed numerous small, white, optic opacities in the IOL and no PFO bubble at fundus examination. The lenticular opacities were unchanged at postoperative month 3 and 6 and no residual PFO was noted in the postremal chamber. The IOL was explanted three months later and a hydrophobic acrylic IOL was implanted in the ciliary sulcus.

Results and discussions

Gross examination of the explanted IOLs showed a whitish discoloration of the specimens. Light microscopy examination showed dense deposits forming an almost a continuous crust, on both surfaces of the optic component.

The results of scanning electron microscopy investigations are shown in the next figures. Because the same aspects were revealed in each clinical case, just the relevant results for our experimental part will be presented.



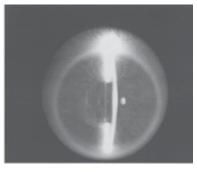


Fig. 1. Slit-lamp view of the anterior segment of the eye showing intraocular lens (IOL) opacification

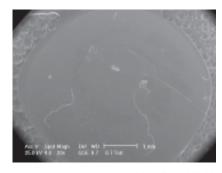


Fig. 2. Scanning electron microscopy image of one explanted IOLs (general view)

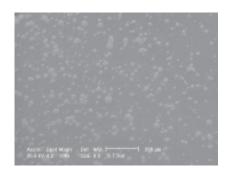
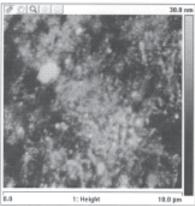


Fig. 3. Scanning electron microscopy image of the optic surface of the lenses



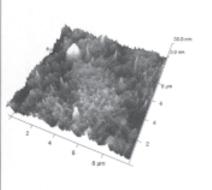
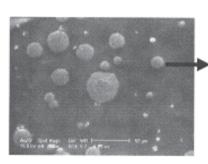


Fig. 4. Atomic force microscopy image of the small area from the optic surface of the lenses



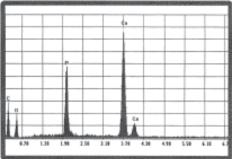


Fig. 5. Scanning electron microscopy image (left) and energy dispersive X-ray (EDS) results (right) on the deposits from the optic surface of the lens

As we could see in figure 1, multiple and small granular deposits were generally observed within the optic and haptics of the lenses, close to the surface. Also, some peripheral areas of the optic were relatively clear of surface and substance deposits/granules.

When we analyze the optic surface of the lenses, we found regular microgranular features and infrequent ridge-like structures over almost entire optic surface of the lenses. The analysis of the small area of this surface who was made using AFM show in evidence the different dimension of the deposits but also we could conclude that on surface are different nanoparticles from different origin.

In order to find the nature of the micro granular features and infrequent ridge-like structures that were observed over almost the entire optic surface of the lenses, we performed an energy dispersive X-ray (EDS) analyses on the deposits. The experimental results, shown in figure 5, demonstrated the presence of peaks of calcium and phosphorus.

Calcification of the intraocular lenses seems to have a multifactorial origin. The formation of calcium deposits seems to depend both on the material of the IOL and on the local chemical microenvironment of the aqueous humor. The etiology of such calcification has not yet been fully understood and may be related to the manufacturing process and even to diseases the patient has. However, other processes may be involved in IOLs made of different materials, such as excessive inflow of water in hydrophobic materials, direct discoloration caused by dyes or medications, and even slow and progressive degradation of the biomaterial [9]. There may be a possible association

between IOL calcification and the metabolic disturbances in diabetes [4,6] as the level of phosphorus in the aqueous humor of diabetic patients, particularly those with proliferative diabetic retinopathy, is significantly higher than normal individuals.

Conclusions

IOL calcification is a sight-threatening complication of lens implantation. When comparing the visual acuity before and after IOL opacification, we noticed that all patients lost more than three Snellen lines in visual acuity.

The crystalline deposition on IOLs can be divided into two general time frames: intraoperative or shortly postoperative versus late postoperative. Our patients had all late postoperative IOL calcification. This means that although the mechanism of this complication is not fully understood, it does not seem to be directly related to substances used during the surgery as it occurred in the late postoperative period. In the first case presented, only one of the lenses exhibited calcification. Both surgical implantations were performed within 1 month by the same surgeon, using the same IOLs. This may suggest that local conditions of supersaturation, either in the vicinity of the surface of the IOLs or within their substance, may promote salts development by diffusion of calcium/phosphate ions, as suggested by other studies too [10].

Not all patients with IOL calcification have underlying systemic diseases [10] – thus the material related association might be another likely explanation. The only effective treatment to restore vision is explantation and

exchange of the calcified IOL. There were no intraoperative complications in all of our cases.

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