ORIGINAL RESEARCH

Case-control study for clinical findings on intraocular lens opacity

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OBJECTIVE: To evaluate clinical features of patients related to opacification of hydrophilic acrylic intraocular lenses, four years after surgery.

METHODS: We evaluated six cases of late opacification of Ioflex intraocular lenses (case group) compared to 24 patients (control group) with no opacification. Both groups underwent phacoemulsification as a result of a community campaign for underprivileged people. Patients who underwent bilateral cataract surgery had only the right eye included on the study. The patients were submitted to ophthalmic examination, including measurements of corrected distance visual acuity and biomicroscopy slitlamp evaluation. Detailed medical histories were obtained. Surgical details were retrieved.

RESULTS: Systemic arterial hypertension was recorded in 4 patients from the case group and 11 in the control group, with no statistically significant difference between groups. A single patient in the control group had diabetes mellitus, and so was not considered for statistical analysis. No environmental factor could be related. There were no statistically significant differences for mean visual acuity between the groups of patients regarding the evaluation periods. One eye in the control group received an Ioflex intraocular lens with the same lot number as one of the opacified lenses.

CONCLUSION: No clear patient factor could be related to late Ioflex lens opacification.

KEYWORDS: Cataract; intraocular lens; postoperative complications.

Jorge PA, Jorge D, Ventura CV, Ventura BV, Lira W, Ventura MC, Santhiago MR, Kara-Junior N. Case-control study for clinical findings on intraocular lens opacity. MEDICALEXPRESS. 2014;1(6):356-358.

Received for publication on August 10 2014; **First review completed on** September 10 2014; **Accepted for publication on** October 29 2014

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INTRODUCTION

Intraocular lens (IOL) opacification is a rare postoperative complication of cataract surgery that can lead to IOL explantation and exchange because of varying degrees of visual loss or of glare symptoms.[1] The most hydrophilic IOL opacification is associated with calcium deposits, either on the surface or infiltrated into the IOL substance.[2,3] Histochemical and microscopical analysis have shown that under favorable conditions, as changes occur in the aqueous milieu surrounding the implanted IOL or because of disruption of the blood-aqueous barrier, infiltration of proteins and cell aggregates might occur and serve as a catalyst or substrate for calcification.[4]

Various pathologic processes may lead to clinically significant opacification of the optic component of IOLs. Coexisting medical illnesses, notably diabetes mellitus and glaucoma have been associated with IOL calcification.[5,6] However, reported research does not have control groups for comparison to determine whether coexisting medical illness are risk factors for IOL calcification.[7,8,9] The aim of this study was to evaluate coexisting medical illnesses related to late Ioflex (Mediphacos, Minas Gerais, Brazil) IOL opacification, a foldable hydrophilic acrylic lens for posterior chamber implantation that has been marketed over ten years in several countries in Europe, Asia and Latin America.[10]

METHODS

This is an observational and case-control study where we evaluated 6 cases of late Ioflex IOL opacification and compared them with 24 patients (control group), in a follow up of 4 years. Both groups underwent phacoemulsification and implantation of the Ioflex IOL as a result of a community campaign for underprivileged people living in the rural area of Pernambuco, Brazil. The case group consisted of the total number of eyes with Ioflex IOL opacification detected; control group patients were randomly selected from the total of 87 eyes submitted to the surgery, as a consequence of a power sample analysis. Exclusion criteria for cataract surgery were blood tension higher than 160 × 90 mmHg

DOI: 10.5935/MedicalExpress.2014.06.12

and glucose level over 150 mg/dl. All patients in the study underwent cataract surgery performed by the same surgeon, using Universal II (Alcon) Phacoemulsifier, with a 2.8 mm incision, under peribulbar anesthesia. Patients who underwent bilateral cataract surgery had only the right eye included on the study, to avoid bias. Operative details, such as surgery complications, were retrieved. Data collected included patient age and sex. Detailed medical histories were obtained. The patients' charts were reviewed for corrected distance visual acuity prior to IOL implantation as well as one month postoperatively. The patients were submitted to an ophthalmic examination, including measurements of corrected distance visual acuity and biomicroscopy slitlamp evaluation, 4 years after surgery.

Visual acuity was measured in Snellen chart notation. For calculation purposes, logMAR values were generated. The Mann-Whitney test was used to study the difference between visual acuity measurements on the evaluation periods. The Fisher's exact test was used to study the difference of arterial hypertension frequency between the two groups of patients. The Friedman test was used to study differences between the mean visual acuity over the evaluation periods.

The study was approved by Altino Ventura Foundation's Ethics Committee (CEP: 054/2011) and followed the Declaration of Helsinki's principles.

RESULTS

Demographic data are shown in Table 1. There was no statistically significant difference between the mean visual acuity of the case and control groups of patients regarding the evaluation periods.

There was no statistically significant difference for the frequency of occurrence of systemic arterial hypertension between patient groups. Arterial hypertension frequency and the kind of medications used by both groups are shown in Table 1. A single patient in the control group and none in the case group had diabetes mellitus, so this patient's data was not considered for statistical analysis. No other systemic disease was recorded. None of the patients had been submitted to another ophthalmic surgery previous to or after phacoemulsification with Ioflex IOL implantation.

Glaucoma was found in 2 patients in the control group. Bullous keratopathy, pterygium, age-related macular degeneration, cystoid macular edema and anterior uveitis were the ophthalmological findings reported in the control group, each by one patient. In the case group, ophthalmological findings reported were severe myopia and asteroid hyalosis, each one in a single patient.

Table 1 - Demographic data and health information in case and control groups.

Variable	Case group ($n = 6$) Number	Control group ($n = 24$) Number	p-value
Age			
Mean (± SD)	74.5(6.5)	67.08(18.03)	
Range	65–84 years	19–86 years	
Occupation			
Retired	5	18	
Farmer	1	6	
Male:Female	3:3	9:15	
Systemic illness			
Hypertension	4	11	0.326
Medication			
Captopril	3	6	
Hidroclorotiazida	1	6	
Furosemida	0	2	
Propranolol	0	2	
Diabetes mellitus	0	1	
Medication			
Metformina	–	1	

DISCUSSION

Various pathologic processes may lead to clinically significant opacification or discoloration of the optic component of intraocular lenses manufactured from different biomaterials and in different designs. Factors such as the patient's associated conditions, the manufacturing process, the method of IOL storage, the surgical technique and adjuvants, or a combination of these may be involved. Hydrophobic materials are specially opacified by excess influx of water, while hydrophilic IOLs are mostly affected by the formation of deposits/precipitates on the IOL surface or within the IOL substance[11,12,13]. Furthermore, direct discoloration by capsular dyes or medications, coating by substances such as ophthalmic ointment and silicone oil, and a slow, progressive degradation of the IOL biomaterial may be involved in the different designs of IOL opacification process.[11]

Delayed-onset IOL calcification has many aspects which remain to be clarified. Reports suggest some systemic diseases as etiologic agents for late IOL opacification, but do not confirm their hypotheses.[9,14,15,16] We found a significant number of patients with arterial hypertension in this study, but there was no correlation between the groups with and without IOL opacification, after 4 years of follow up. Hypertension is a common finding in a senior population; however, detailed investigations of blood and aqueous chemistry in these cases would be helpful in identifying metabolic disturbances that might contribute to dystrophic calcification, mainly if it plays a role in the breakdown of the blood-aqueous barrier.

The mechanisms of intrinsic and extrinsic calcification described in the literature may not suffice to differentiate between a problem in the IOL itself leading to calcification (be it mediated by proteins, contaminants, or directly) and those cases that occur because of environmental circumstances.[11,17] Papers evaluating medical illness in association with IOL opacification suggest that a mechanism of blood-aqueous barrier impairment seemed to be associated with this postsurgical complication.[18] According to the literature, hydrophilic acrylic IOLs are likely to develop calcification when the concentrations of calcium, phosphate and albumin in the aqueous humor fluctuate due to blood-aqueous-barrier breakdown or other factors. Because the aqueous humor turns over every 90 minutes, it is significantly affected by concentrations of elements in the blood.[9] That is why long-term observation is necessary after implantation of hydrophilic acrylic IOLs, especially in cases in which blood-aqueous barrier breakdown is suspected, as may occur in diabetes, uveitis and vitrectomy.[19,20]

The IOL opacification/discoloration has also been associated with the long-term use of systemic medications. Amiodarona and rifabutin had already been reported in patients with opacified lenses.[21,22] The interaction of ophthalmic medications was also related with intraocular

lenses opacification of different materials.[23] However, we did not find any correlation with systemic medications reported by the patients of both groups and the opacified IOLs.

Some authors suggest that premature aging of the ultraviolet blocking agent incorporated in the lens biomaterial could be the cause of the IOL opacification[24] but have not confirmed their hypotheses. In this study Frohn et al. also suggest that characteristics of the patients play a possible role in the origin of the phenomenon, but they exclude systemic disease and drugs as sources for opacification because they were not common in all cases.

In our study, both groups were from the same region, which is hot and dry year-round and has agriculture as its predominant economic activity. As the sample evaluated was mostly composed of retired elderly people living under the same environmental conditions and having similar eating habits, these environmental factors become improbable as etiologic agents for this complication.

This study's limitation is the small size of the evaluated sample; however, the IOL opacification either has a small incidence in the literature, or the Ioflex IOL opacification is underreported.[12,25] Furthermore, the random occurrence of late hydrophilic acrylic lenses opacification and its unknown etiology is another challenge. In conclusion, no clear patient factor could be identified in relation to Ioflex IOL opacification. Observational and case-control studies must be repeated in order to arrive at new significant answers.

RESUMO

OBJETIVO: Avaliar as características clínicas relacionadas à opacificação tardia de lente intraocular (LIO) acrílica hidrofílica, quatro anos após a cirurgia.

MÉTODOS: Foram avaliados seis casos de opacificação tardia de Lentes Intraoculares Ioflex, comparados com 24 pacientes (grupo controle). Ambos os grupos realizaram facoemulsificação em uma campanha comunitária para pessoas carentes, em Pernambuco, Brasil. Pacientes que operaram os dois olhos tiveram apenas o olho direito incluído no estudo para evitar vieses. Os pacientes foram submetidos a exame oftalmológico incluindo medida da acuidade visual corrigida para distância e exame biomicroscópico na lâmpada de fenda. O histórico médico detalhado dos pacientes e os detalhes da cirurgia foram obtidos.

RESULTADOS: Quatro pacientes apresentaram hipertensão arterial sistêmica no grupo de casos e onze no grupo controle. Não houve diferença estatisticamente significante entre a freqüência da hipertensão arterial entre ambos os grupos. Apenas um paciente do grupo controle apresentou diabetes; por isso, não foi considerado para análise estatística. Nenhum fator ambiental foi relacionado. Não houve diferença estatisticamente significante entre as médias da acuidade visual de ambos os grupos nos períodos em que foram analisados. Um olho no grupo controle apresentou o mesmo número de lote de uma das Lentes Intraoculares opacificadas.

CONCLUSÃO: Nenhum fator clínico dos pacientes apresentou relação com a opacificação tardia da Lente Intraocular Ioflex.

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