Glaucoma and Corneal Decompensation Following Cosmetic Iris Prosthesis Implantation: A Case Report

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Abstract

Purpose: This case report illustrates the difficult management of complications produced following the bilateral iris implant of the NewColorIris (NewColorIris, Kahn, and Medical Devices).

Methods: We report the case of a 36-year-old man who was referred to our outpatient clinic because of bilateral glaucoma showing a poor response to medical treatment and anti-glaucoma surgery. The young man had received an iris implant (NewColorIris, Kahn, Medical Devices) in both eyes for cosmetic purposes 5 years earlier. Surprisingly, his clinical records revealed a strictly normal ophthalmologic examination (visual acuity (VA) was 20/20 in both eyes) following NewColorIris explantation. Subsequent to this the patient required new artificial iris implantation, 2 anti-glaucoma surgeries (trabeculectomy+Ex-press®shunt placement) and cataract surgery in both eyes, and DSAEK in the left eye. On presentation, his VA was 20/200 in both eyes, endothelial cell count was less than 1000 and he showed diffuse corneal edema, iris retraction, anterior synechiae, iris implant in the sulcus, multifocal IOL and an intraocular pressure of 40 mmHg in both eyes.

Results: Poor pressure control was resolved through Ahmed valve placement in both eyes though his vision remains poor.

Conclusions: This clinical case highlights the serious, poorly manageable, irreversible complications produced by the NewColorIris implant.

INTRODUCTION

Iris implants are intraocular prostheses that mimic the morphology and functions of the healthy iris [1,2]. Such implants have been successfully used to resolve iris diseases and with improving surgical techniques, their use for cosmetic purposes has also started to gain popularity. The cosmetic implants NewColorIris marketed by Kahn Medical Devices (Panama City, Panama) were introduced as a safe alternative to colored contact lenses for purely cosmetic use in healthy individuals (with no history of eye disease). There are three color-options available (hazel, green or blue).

These non-US Food and Drug Administration–approved cosmetic implants have nevertheless been associated with several serious complications: corneal edema, increased intraocular pressure (IOP), pigment dispersion, uveitis, a reduced endothelial cell count, uveitis–glaucoma–hyphema syndrome, glaucomatous
optic neuropathy, cystoid macular edema, trabecular meshwork damage, and suprachoroidal hemorrhage. Since their initial use in 2004, these complications have been widely described in the literature [2-6].

Many complications following NewColorIris implantation are difficult to manage in the long term and may give rise to permanent sequelae. Besides implant removal, the control of these complications requires multiple surgical procedures and the visual prognosis is uncertain.

We here report a clinical case that clearly shows the difficult management of complications produced following the bilateral implant of the NewColorIris. Besides explantation, the patient here described required a series of complex surgical procedures to stabilize clinical symptoms and avoid progressive vision loss.

CASE REPORT

A 36-year-old man who had undergone NewColorIris (Kahn, Medical Devices) implantation in both eyes 5 years earlier (in Panama) was referred to our outpatient clinic because of progressive vision loss.

The patient had been treated one year after the iris implantation surgery by a cornea and glaucoma specialist, who removed the implants from both eyes without additional complications. The reason for explantation was the observation of anterior chamber inflammation, anterior synechiae, cataract, and an endothelial cell count under 1000 in both eyes. Following explantation, intense iris retraction leaving scar remains of the iris and 360 °C of anterior synechiae were detected.

Subsequent to implant removal, the patient underwent cataract extraction with multifocal intraocular lens (IOL) placement in both eyes. Upon request of the patient and due to intense photophobia, an artificial iris HMK ANI 2 (Ophtec/ Polytech) was implanted in the sulcus in both eyes. Due to poor IOP control using eye drops, the patient underwent implantation of an Ex-press® shunt under a scleral flap on two occasions per eye (first in the temporal superior zone and then in the nasal superior zone). Finally, due to corneal decompensation, the left eye was subjected to Descemet’s stripping automated endothelial keratoplasty (DSAEK).

On examination at presentation, the patient was under treatment with brimonidine and timolol eye drops twice a day in both eyes and oral acetazolamide 250 mg three times per day. Best-corrected visual acuity (BCVA) was 20/200 in both eyes. Slit lamp examination revealed iris retraction and anterior synechiae along with an HMK ANI 2 implant in both eyes. In each eye, the multifocal IOL could be seen along with two Ex-press® filtration devices in the temporal superior and nasal superior quadrants. The DSAEK endothelial graft was observed in the left eye (LE) (Figure 1). A low endothelial cell count was obtained in the RE (850 cells/mm²). Fundoscopy examination revealed a cup-to-disc ratio of 0.4-0.5 in both eyes and no macular or retinal abnormalities. In both eyes, IOP was 40 mmHg and the patient reported IOP fluctuations from 5 to 45 mmHg. Visual field testing revealed a mild visual field defect and retinal nerve fiber layer thinning in the superior and inferior zones was detected in both eyes by optical coherence tomography (OCT).

To control the severe IOP fluctuations refractory to pharmacological treatment, an Ahmed valve was implanted in the temporal zone behind the iris remnant, in front of the iris prosthesis in both eyes (Figure 2).

Three months after presentation, the patient has an IOP of 10-12 mmHg in both eyes and BCVA is 20/400 in the RE and counting fingers at 2 m in the LE. At the time of writing, corneal turbidity detected in the LE suggests further surgery will be required to improve visual acuity (Figure 3).

DISCUSSION

The NewColorIris implant is a silicone, ring-shaped, one-piece diaphragm with 6 semicircular peripheral footplates, or flaps. It is available in one size only, measuring 15.00 mm in diameter, with a central pupil hole of diameter 3.50 mm and thickness of 0.16 mm. However, despite the standard design, individual variation seems common. According to Hoguet et al, [6], “the implants were not identical and some, but not all, have peripheral iridectomy cutouts of various sizes”. Also, Anderson et
al., [3], reported irregular sharp edges observed by microscopy and also stated that not all implants had 6 footplates.

The implant is designed for anterior chamber placement in phakic eyes. Based on the long-standing use of phakic intraocular lenses, it is well known that any anterior segment implant needs to be suitably fitted to the size of the chamber to avoid the high morbidity and vision loss produced by inadequate fitting [3-7].

There are numerous reasons for the serious complications arising from NewColorIris implantation. Initial symptoms, most often reddening and blurred vision, may appear within 6 months of surgery though usually they appear within the first 2 years [3-6]. Once initial signs arise, management usually involves implant removal. Although explantation is not usually difficult, some complications have been described such as crystalline lens opacification, cystic macular edema and even suprachoroidal hemorrhage [6].

The use of cosmetic iris implants has also been linked to significant endothelial cell loss [7]. Cell loss commences as soon as the implant is inserted and unfolded in the anterior chamber [3]. Some authors have described the instability and movement of the prosthesis in the anterior chamber and decentration with respect to the pupil can occur [3,6].

Although endothelial cell loss occurs in practically all cases, only a few implants following their removal will give rise to corneal decompensation resulting in a low visual acuity that may require a corneal transplant, preferably DSAEK or a penetrating keratoplasty [6].

The onset of ocular hypertension or glaucoma is also a frequent complication. Among the many factors possibly leading to an increase in IOP [1], instead of haptics, the NewColorIris has 6 footplates that rest on the corneal-scleral angle damaging the trabecular meshwork, Schlemm canal and collector channels.

Several authors have described by means of anterior chamber OCT and ultrasound biomicroscopy [3,7] the direct contact of the implant with the iris which, added to its movement, promotes pigment dispersion. In effect, this could be the initial IOP elevation mechanism. Further, the irregular implant surface will enhance pigment dispersion [3,7]. Inflammation, pigment accumulation, hyphema and corticoid use are the main factors that lead to this type of open-angle glaucoma [5]. However, although less frequent, cases of angle closure have been related to anterior synchiae sometimes affecting 360 degrees. This irreversible situation even arising after explantation may rarely be accompanied by iris retraction, as observed in our patient. A much more frequent complication is cataract requiring surgery [3,6].

Our clinical case illustrates the series of complicated surgeries needed because of the implant of this prosthesis in a young, healthy, phakic individual. Despite explantation, surgical treatment was needed for corneal decompensation, cataract, complete iris retraction and glaucoma showing poor pressure control.

In this clinical case, owing to the intense photophobia produced by severe iris retraction and according to the patient’s wishes after NewColorIris explantation, we decided to pursue the sulcus implant of a HMK ANI 2 artificial iris. This is among the several safe and efficient options currently available for iris reconstruction. It is important to distinguish between the NewColorIris implant and existing safe prosthetic iris models. In general, these models are used in aphakic or pseudophakic patients with congenital or posttraumatic iris abnormalities and have received Conformity European (CE) marking [7].

In cases of difficult glaucoma control, a valve implant is the surgical treatment of choice. Complete angular closure determines a poor response to filtering surgery. In the present patient, several operations to implant an Ex-press® shunt were unsuccessful and we finally opted for an Ahmed valve. Posterior chamber implant of this device is always preferable, especially in a case such as the present involving prior DSAEK surgery. Given the intense retraction of the iris shown by our patient, we positioned the Ahmed valve tube behind the iris remnant, in front of the new prosthesis.

In summary, the NewColorIris implant gives rise to serious irreversible complications that are poorly manageable. The final outcome of such complications is usually severe morbidity accompanied by poor vision. We recommend that the use of cosmetic implants should be avoided at all costs.

REFERENCES

Cite this article