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Case Report

BrightOcular® Cosmetic Iris Implant: A Spectrum from Tolerability to Severe Morbidity

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Cosmetic iris implants · BrightOcular® iris implant · Tolerability · Safety

Abstract
Purpose: The BrightOcular® implants are the newest model of cosmetic iris devices that are currently advertised as safe. The previous generation known as NewColorIris® have had severe ocular side effects and were subsequently withdrawn from the market. There is little literature on the safety profile of BrightOcular® implants. ***Case Report:*** Herein we describe two cases with varying degrees of ocular tolerability. The first case had a normal ocular exam 1 year after implantation, whereas the second case had unilateral severe corneal edema requiring explantation of the iris device and Descemet membrane endothelial keratoplasty 9 months after bilateral implantation. ***Conclusions:*** These two cases attest to the unpredictability of the results of these cosmetic surgeries. Patients should be counseled about the vision-threatening complications of iris implants.

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Introduction

BrightOcular® implants (Stellar Devices, New York, NY, USA, US patent 2012 #8197540) are a new generation of implants that are advertised to be a safer than previous models (notably NewColorIris® by Kahn Medical Devices, Panama City, Panama, US patent 2006 #7025781 2B) associated with severe sight-threatening ocular pathology [1–5]. The literature [6–9] has only a few reports that describe severe ocular side effects from BrightOcular® implants. This report focuses on the wide spectrum of outcomes of BrightOcular® iris implants ranging from tolerability of the device to serious ocular pathology, and hence the need to individualize the management of these patients.

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Case 1

This 39-year-old Caucasian woman presented with complaint of floaters. She had had laser in situ keratomileusis (LASIK) surgery for high myopia in India. She had had bilateral BrightOcular® iris implant 1 year prior to presentation. Best corrected visual acuity was 6/7.5 (20/25) in both eyes with a manifest refraction of –6.00 –0.75 ×45° in the right eye and –4.25 –1.00 ×130° in the left eye. Intraocular pressure measured 17 mm Hg in the right eye and 15 mm Hg in the left eye. Slit-lamp examination revealed a quiet anterior segment in both eyes, clear corneas, and well-centered BrightOcular® implants (Fig. 1). Both eyes were phakic with no cataract. Fundus exam revealed unremarkable posterior pole with cup/disc of 0.4 and limited view of the retinal midperiphery. Gonioscopy showed open angles (Schaffer grading 3) in both eyes. Retinal nerve fiber layer thickness by optical coherence tomography (OCT) was 84 μm in the right eye and 85 μm in the left eye. Using anterior segment optical coherence tomography (AS-OCT), anterior chamber depth was 3.29 mm in the right eye and 3.38 mm in the left eye and moreover, the iris diaphragm showed no impingement of the angle (Fig. 1). Visual fields were constricted from the fixed pupillary opening (Fig. 2). Specular microscopy demonstrated a normal endothelial cell count (central corneal endothelial count 2,471 cells/mm^2 in the right eye and 2,338 cells/mm^2 in the left eye) with normal morphology in both eyes (Fig. 3). Central corneal pachymetry was 553 μm bilaterally. No treatment was given besides close monitoring. The exam was unchanged at the last follow-up at 12 months.

Case 2

This 36-year-old Caucasian woman presented with blurry vision in the left eye of 3 months' duration. She had had bilateral BrightOcular® implantation 9 months prior to presentation. Best corrected visual acuity was 6/6 (20/20) in the right eye and counting fingers at 1 m in the left eye. Intraocular pressure was 11 mm Hg bilaterally. She had bilateral iris implants with a clear cornea and quiet anterior chamber in the right eye. The left eye had diffuse epithelial corneal edema with deep anterior chamber and a well-centered iris implant. Gonioscopy revealed an open angle (Schaffer grade 3) in the right eye and hazy view in the left eye. The patient was phakic in both eyes with no cataract. There was poor visualization of the left fundus with normal fundus exam in the right eye and cup/disc of 0.2.

Specular microscopy of the right eye showed decreased endothelial cell density (1,121 cells/mm^2) without cellular polymorphism (coefficient of variation 25%, hexagonal cells 68%). Specular microscopy did not provide accurate left corneal measurement due to marked

stromal edema. AS-OCT demonstrated thickening of the left central cornea (834 μm) compared to the right central cornea (540 μm) (Fig. 4).

The left eye underwent Descemet membrane endothelial keratoplasty as previously described [10] with explantation of the iris implant 3 days after presentation using bimanual "slicing the pie" technique with microscissors and microforceps [11] and leaving the clear lens. Initially she was placed on hourly combination of tobramycin and dexamethasone drops and this regimen was tapered slowly over the following 2 months. The graft remained attached and there was no need for rebubbling. The lens remained clear postoperatively. No treatment was done to the right eye.

Uncorrected visual acuity improved to 6/12 (20/40) on day 1 and 6/6 (20/20) at the last follow-up 2 months after surgery. Manifest refraction at 2 months was plano in the right eye and –0.50 dpt in the left eye. The left cornea improved clinically by recovery of the endothelial count (1,931 cells/mm^2) and decrease in corneal thickness (interval decrease of 123 μm). The patient was lost to follow-up.

Discussion

Despite an abundance of reports on the complications associated with NewColorIris® [1–5], only few reports are found in the literature to recount the side effects of BrightOcular® [6–9]. These devices are not Food and Drug Agency (FDA) approved [8]. BrightOcular® implants are made of medical-grade silicon with patented posterior grooves to facilitate continuous flow of aqueous humor and minimize iris chaffing [6–9]. Moreover, BrightOcular® implants come in different sizes (12 and 12.5 mm) making it possible to individualize the device according to white-to-white measurements [6]. These modifications are meant to minimize the sight-threatening complications noted with NewColorIris® [8]. Despite these important modifications, Mansour et al. [8] in 2016 collected 12 patients having this implant and the complications included uveitis (83%), angle closure glaucoma (58%), and corneal decompensation (50%). They also reported permanent iris atrophy and pupillary abnormalities after explantation of the device [8]. Only a single case in that series was asymptomatic and did not require surgical intervention [8]. Single case reports also showed examples of angle crowding leading to glaucoma or corneal decompensation [7, 9].

Whereas the patient in Case 1 had normal findings 1 year postoperatively, Case 2 reported symptoms in a single eye 6 months postoperatively. Mansour et al. [8] reported that complications with BrightOcular® showed up as soon as 1 month postoperatively and as late as 2 years. Most patients had signs of ocular comorbidity at a median of 12 months after implantation [8]. In contrast, Arjmand et al. [11] recount a case of NewColorIris® complications observed as late as 5 years after implantation. One eye in Case 2 had corneal decompensation and was treated with explantation and Descemet membrane endothelial keratoplasty with full recovery of vision. The explantation technique varies among surgeons and was described for the NewColorIris® implants; some surgeons use a "slicing-the-pie" technique to cut the implant with microscissors into three pieces with viscoelastic coverage and then extracting each piece alone through a 2-mm corneal incision [11]. Others chose a larger corneal wound (5–6 mm) and produce a sphincterotomy in the implant before removing it all in one piece [5].

In the current report, three out of the four eyes with the iris implant had a normal eye exam. We speculate thus that despite problematic past experiences with older models, BrightOcular® implants may be tolerated by some patients depending on factors that are so far undetermined. It could be related to a mechanical and anatomical match between the

angles and the diameters of the implant relative to the host eye, which can decrease the risk of trabecular compression, or endothelial touch [1]. Oversized implants tend to erode the iris root leading to peripheral iris atrophy, iritis, and pigment dispersion glaucoma [1]. Proper patient selection would limit such complication. Also, use of current technology to visualize the angle and measuring white-to-white dimension seems imperative before any cosmetic iris implantation. Moreover, refining surgical techniques of implantation can decrease surgical trauma to the iris and cornea. Long-term data are still lacking for the BrightOcular® implants and it is imperative to follow up these cases for life. Patients seeking such implants need to be counselled about the potential blinding sequelae. Cosmetic iris implants hamper future surgical intervention to cornea, lens, and retina.

Statement of Ethics

The subjects of this case report provided informed consent for the publication.

Disclosure Statement

The authors have no financial or proprietary interest in the material presented herein.

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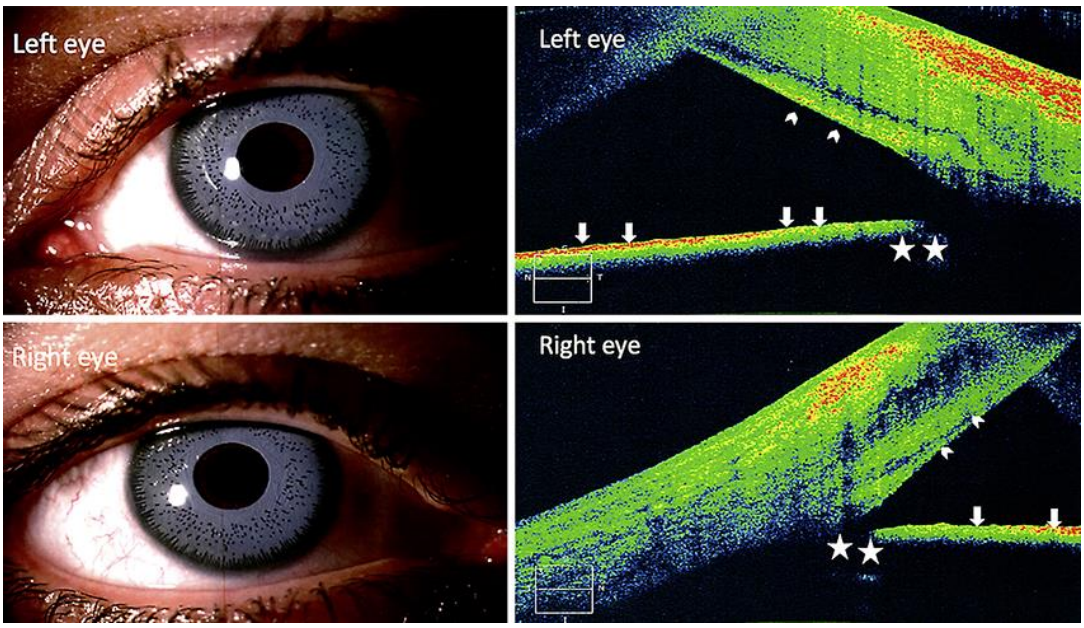

Fig. 1. Left side: Anterior segment photographs of Case 1 one year after bilateral cosmetic BrightOcular® iris implantation. Right side: Anterior segment optical coherence tomography showing the iris implants (arrows) abutting the iris surfaces (stars), with open angles and normal corneal appearance (arrowheads).

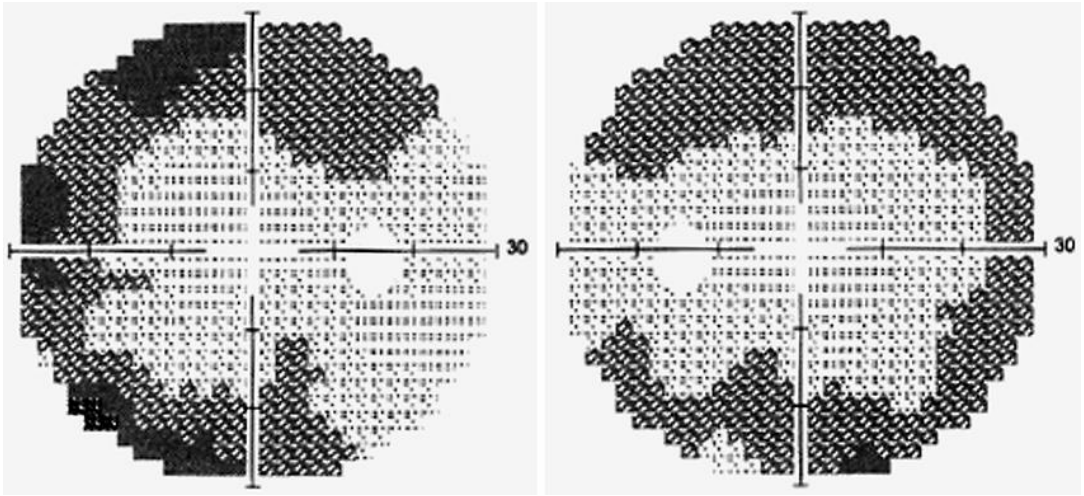

Fig. 2. Right eye (left image) and left eye (right image) visual field results of Case 1 showing bilateral symmetrical visual field constriction due to the fixed pupillary diameter imposed by the cosmetic iris implant.

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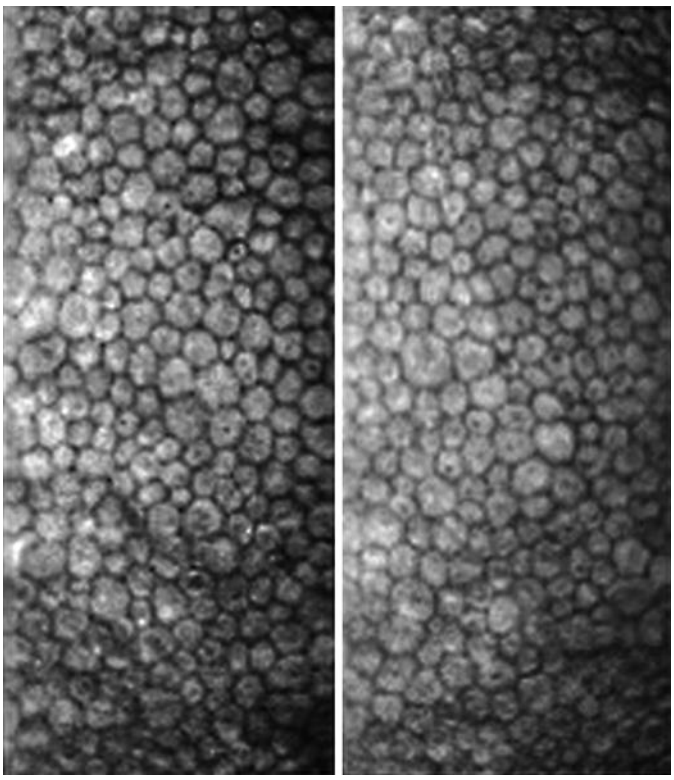

Fig. 3. Right eye (left image) and left eye (right image) specular microscopy of Case 1 showing an endothelial count of 2,471 cells/mm^2 with coefficient of variance 39% and hexagonal cells 52% in the right eye and an endothelial count of 2,338 cells/mm^2 with coefficient of variance 38% and hexagonal cells 47% in the left eye.

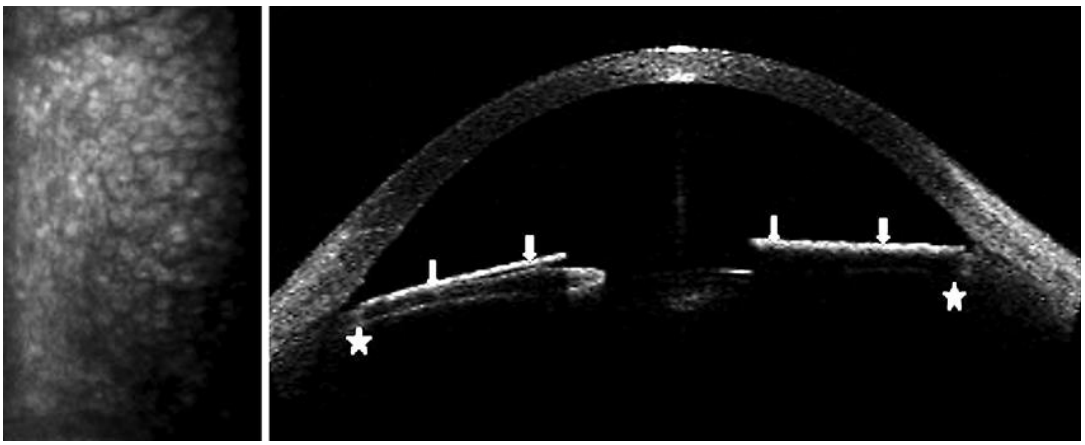

Fig. 4. Right eye data of Case 2. Left image is the specular microscopy showing an endothelial count of 1,121 cells/mm^2 with coefficient of variance 25% and hexagonal cells 68% in the right eye. Right image is the anterior segment optical coherence tomography (AS-OCT) showing open angles with the iris implant (arrows) on top of iris plane (stars) thickness. The left-eye specular microscopy and AS-OCT were unavailable due to corneal decompensation.