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CASE REPORT

Management of complications of cosmetic iris implants in a phakic eye: a case report and literature review

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Abstract
Purpose To report the intricacies of managing complications that arose out of cosmetic iris implants (BrightOcular) placement.
Design Interventional case report.
Methods A thirty-year-old gentleman presented with complaint of progressive loss of vision after having cosmetic iris implant surgery to change his eye colour. He then developed raised intraocular pressures and had a right eye trabeculectomy conducted with the implants in situ. Subsequently, he had implant removal surgery because of persistent implant-associated complications. The vision was impaired due to progressive corneal oedema and glaucoma. Various considerations were taken while planning for surgical intervention because of the extensive structural damage to the anterior segment of the eye.
Conclusion This case report highlights that cosmetic iris implants are dangerous intraocular devices and management of the associated complications is also challenging. As these devices cause irreversible structural and functional damage, their use should be discouraged in normal eyes.

Keywords Iris implants · Cosmetic iris · Colour changing

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Introduction

Silicone anterior chamber iris implants, the NewColorIris, were first developed by Kahn in 2004 mainly for patients with ocular albinism for cosmetic purposes and at the same time, reduction of symptoms such as glare and photophobia [1]. Nevertheless, the implants gained more popularity with clinically normal phakic patients who sought to change their eye colour [2, 3].

Several case reports and series have documented complications associated with these implants [4, 5]. They were then phased out and replaced with the BrightOcular implant which was promoted as having improvements in design. These changes may have partially corrected the problems encountered with the NewColorIris devices and in theory are thought to have reduced the complication rate [5, 6].

We describe a case of corneal decompensation, glaucoma and cataract secondary to cosmetic iris implantation with a highlight on the challenges in managing these complications.

Case report

A thirty-year-old male presented to our institute with progressive loss of vision over one and a half years. He had undergone cosmetic iris (BrightOcular) implantation elsewhere 3 years earlier to change his eye colour from brown to grey. His records showed that he had normal anterior segment findings in both eyes prior to undergoing cosmetic iris implants. One year after the implant surgery, he developed blurring of vision and intermittent redness in both eyes and was diagnosed to have iritis that was treated with topical corticosteroids. He thereafter developed secondary glaucoma and was started on topical anti-glaucoma medications. However, the right eye intraocular pressure could not be controlled medically, and he underwent trabeculectomy with the implant in situ. Due to progressive loss of vision and corneal decompensation, the implants were removed 3 years after implantation.

His vision at presentation was 20/800 in the right eye and 20/80 in the left eye. The intraocular pressure (IOP) measured with Goldmann Applanation Tonometry (GAT) was 16 and 18 mmHg in right and left eyes, respectively. Slit-lamp examination revealed bilateral corneal oedema, extensive broad peripheral anterior synechiae in inferior, nasal and temporal regions with a shallow anterior chamber of irregular depth (Fig. 1a, b). The right eye had a cataract and advanced glaucomatous optic neuropathy. The left optic disc was not visible due to corneal oedema. An impression of bilateral corneal decompensation and secondary glaucoma status post BrightOcular explantation was made, and he was advised to undergo Descemet's stripping automated endothelial keratoplasty (DSAEK) in both eyes. It was decided to operate the left eye first for faster visual rehabilitation, and this was done 2 weeks later.

Intra-operatively, a superior clear corneal incision was made avoiding the area of broad peripheral anterior synechiae, and an anterior chamber maintainer was used to maintain the anterior chamber depth while Descemet's membrane scoring was being done. The lenticule was sized so as to ensure that it would not extend to the areas of peripheral anterior synechiae and that the pupil would be well centred. The immediate post-operative vision improved to 20/60. Post-operatively, he was treated with topical antibiotics for a week and tapering dose of topical corticosteroids.

In the post-operative follow-up period, he developed a steroid response despite use of a low potency topical steroid (Loteprednol etabonate 0.5% eye drops) and his IOP could not be controlled by maximally tolerated anti-glaucoma medications. The IOP was noted to fluctuate between 15 and 35 mm Hg using GAT, with progressive structural and functional damage which was confirmed on automated perimetry using the Humphrey Visual Field (HVF) (Figs. 2 and 3).

For these reasons, we opted for Mitomycin C augmented trabeculectomy for the left eye. The surgery was performed using Khaw's technique [7, 8] with a rectangular scleral flap, and 0.02% Mitomycin C applied for 1 min. A releasable suture was applied to the scleral flap to avoid early post-operative hypotony. He developed Tenon's cyst in the post-operative period that responded well to digital ocular massage, and no further intervention was required for the control of IOP.

Right eye combined DSAEK and cataract surgery (phacoemulsification) was performed 2 months after his initial presentation. A similar approach was taken with a superior clear corneal incision to avoid the bleb. Graft was sized and centred to the pupil as much that possible. Post-operatively, a tapering dose of a low potency steroid was prescribed.

At his latest review 1 year after the initial presentation, the visual acuity was 20/40 in the right eye and 20/20p with a spectacle correction of -1.00DC $\times$ 90° in the left eye. The intraocular pressure was well controlled (18 mmHg) with the right eye on two anti-glaucoma medications (Brimonidine/Timolol maleate 0.2%/0.5% eye drops twice daily, and Pilocarpine 2.0% eye drops once daily). The blebs were shallow, diffuse, and the lenticule was well attached in both eyes.

The right eye optic disc was noted to have near total cupping, whereas the left eye had bipolar excavation. Additional prescribed medication consisted of low-dose topical corticosteroids: Loteprednol 0.5% eye drops twice daily and Tacliment 0.03% ointment applied at night as a steroid sparing agent. The patient was counselled on the importance of regular treatment and follow-up with the glaucoma/cornea team to keep a close watch on the health of the lamellar corneal graft and monitoring of intraocular pressures.

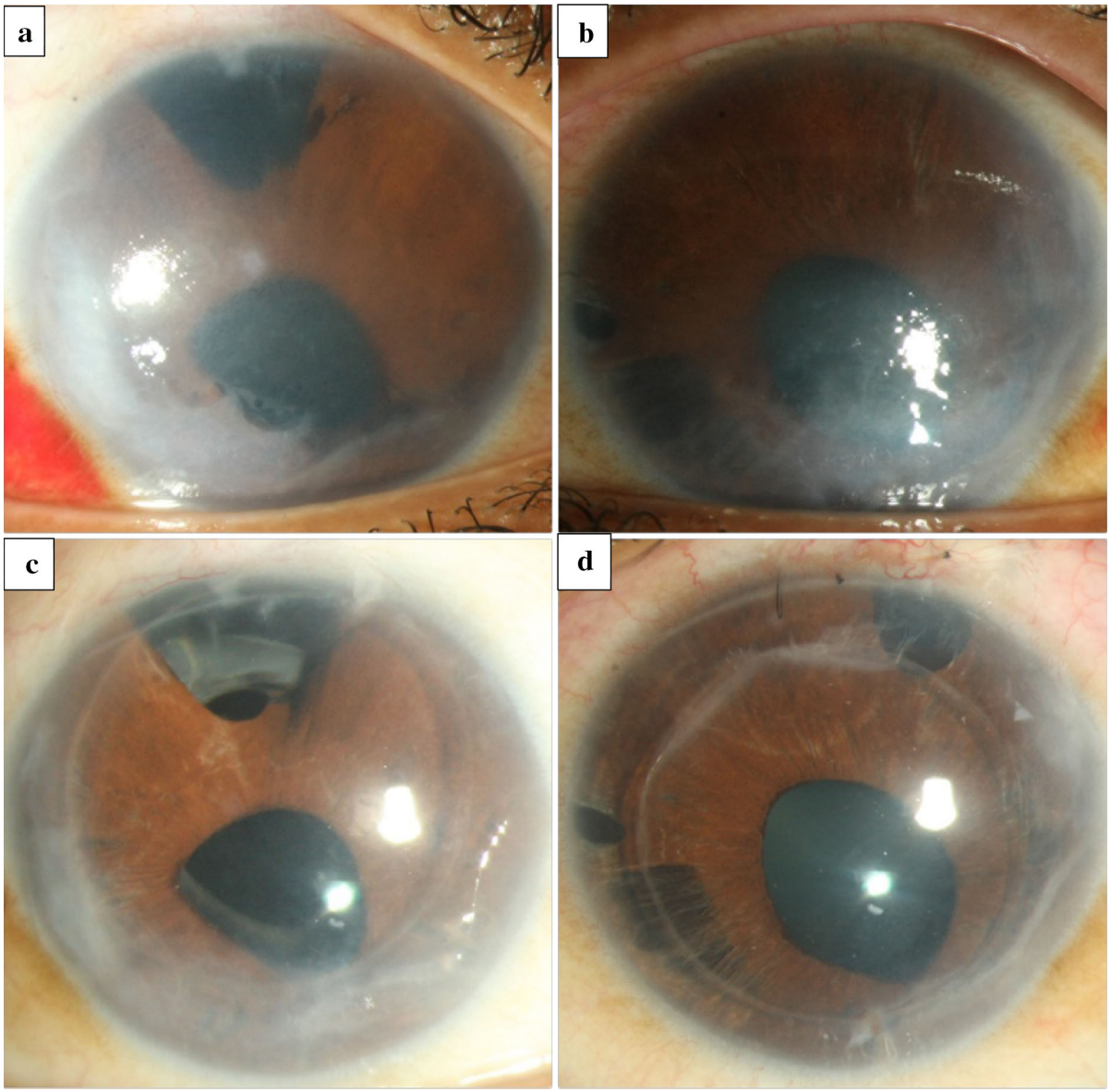

Fig. 1 **a–d** Diffuse illumination slit-lamp images showing pre-operative views of the right (**a**) and left eye (**b**). Images **c** and **d** show post-operative views of the right and left eye, respectively

Discussion

The search for beauty has ever been so elusive with an increasing number of people searching for ways to permanently change their eye colour. Because of this, cosmetic iris implants have slowly gained popularity in spite of the increasing number of case reports and case series documenting a rise in patients presenting with complications. This could be explained by the fact that there is a lot of internet and TV marketing which gives the false impression that the implants are FDA approved and the risk of complication is like other intraocular surgeries such as phakic intraocular lens implantation. They are popularised on the BrightOcular website (www.brightocular.com) by people including celebrities giving testimonials on how their lives have changed for the better since getting the "Colour changing" iris implant surgery.

There are few data published on the complications associated with these implants but those reported more

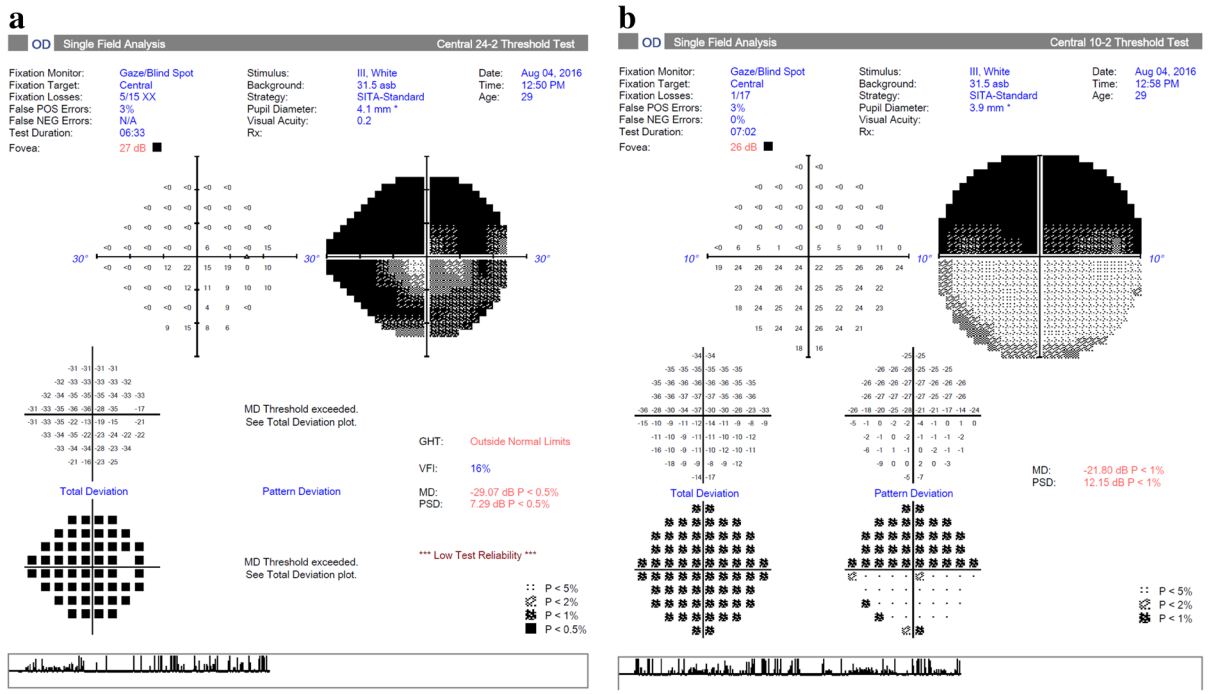

Fig. 2 Right eye HVF (**a** 30-2, **b** 10-2) showing a complete bi-arcuate scotoma involving fixation

commonly include: endothelial decompensation, prolonged iritis, intraocular pressure rise, iris damage with formation of peripheral anterior synechiae leading to corectopia, cataractous lens changes and glaucomatous disc atrophy [2, 4, 5]. These complications tend to occur simultaneously. A systematic review of studies reporting post-operative outcomes of cosmetic iris implants carried out by Galvis et al. found that the most common complication described in the 128 previously healthy eyes was glaucoma (59 eyes), closely followed by severe endothelial cell loss with or without corneal decompensation (44 eyes) [5]. Hoquet et al. reported the largest case series of 14 eyes who had NewColorIris implants; all 14 eyes had explantation of the devices 4–33 months after placement [4]. These implants lead to permanent structural damage which contradicts what is stated on the official website that the implants are safe and reversible. It has been reported that as long as the implants are in, complications can occur even years after implantation [3, 4].

Many surgeons have suggested ways of explanting the implants and at the same time minimising collateral damage. It is recommended at the time of explantation; only implant removal should be done, leaving further surgical intervention to be carried out at a different sitting. Sikder et al. described a surgical technique for NewColorIris implant removal in which they recommended removal of the implant through a 2.75 mm temporal clear corneal incision after cutting the implant into three equal parts [8]. Arjmand et al. described the "slicing-the-pie" bimanual technique of implant removal through 2.0 mm small incisions with minimal implant manipulation and use of soft-shell ophthalmic visco-surgical device to minimise anterior chamber shallowing in order to protect the endothelium [9].

After implant removal, it is important to assess these patients well and keep a close follow-up to assess the need for further interventions. Firstly, endothelial keratoplasty can be done to reduce the symptoms and the loss of vision secondary to endothelial decompensation. Galvin and team in their review found that 26/128 (20.3%) of the eyes required corneal transplantation with the majority undergoing endothelial keratoplasty [5]. Secondly, glaucoma surgery may be needed when the intraocular pressure cannot be medically controlled. Hoguet et al. found that although explantation helped stabilise symptoms, additional medical and surgical interventions were needed to

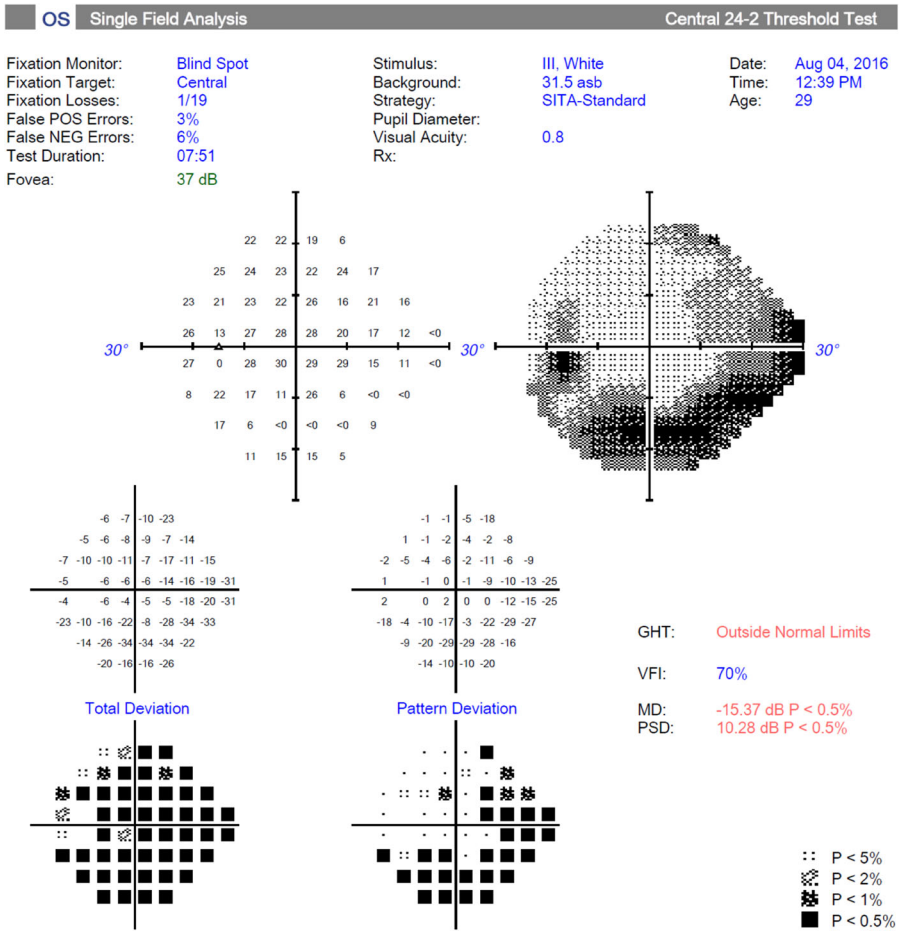

Fig. 3 Left eye HVF (30-2) showing and incomplete bi-arcuate scotoma

control IOP and trabeculectomy was carried out in 3 of the 14 eyes and glaucoma drainage implant placement in the three eyes [4]. Thirdly, cataract surgery may be required because cataract may also occur as a complication. Lastly and ironically, cosmetic surgery with medically approved cosmetic iris implants may need to be done where suitable to improve the cosmetic appearance because there is usually significant iris damage.

Our patient developed bilateral prolonged iritis, secondary glaucoma, corneal decompensation and a left eye cataract. This was similar to what was found by Galvin et al. that many eyes reviewed in their series had concurrent complications [5]. The presence of extensive, broad, and fibrosed peripheral anterior synechiae, led to a gross distortion of anterior chamber anatomy. Both eyes had a crowded anterior chamber because of the broad peripheral anterior synechiae. In addition, the right eye had a large broad iridectomy and a significant cataract that needed a combined cataract surgery along with endothelial keratoplasty. The left eye had a clear lens necessitating minimal intraocular movements and manipulation to prevent lens damage. Various modifications were considered during DSAEK in both eyes. First, a superior clear corneal incision site was decided to avoid the bleb in the right eye and an anticipated need for glaucoma filtration surgery later in the left eye. A temporal approach was not an option in view of broad extensive synechiae in that region. Second, graft sizing and centration to the pupil was a challenge because of the 180 degrees of broad densely fibrosed peripheral anterior synechiae and resultant corectopia. Synechiolysis was deferred as it would have led to excessive intraocular bleeding, compromising the anterior chamber visualisation and increasing the risk of

interface haze post-operatively. The lenticule was sized and placed in a favourable position to get a good coverage of the pupillary area. The endothelial keratoplasty and glaucoma surgeries were successful although unfortunately the patient had advanced glaucomatous disc damage.

This case shows that managing complications as a result of cosmetic AC iris implants and removal surgery can be quite challenging because of the resultant structural damage and also the need to have some forethought of the possible need for further surgical intervention. Therefore, this necessitates meticulous planning to avoid the need for multiple interventions where possible. Counselling the patient on the importance of proper follow-up after the surgical intervention is very important to keep watch on the graft health. Glaucoma control is also key to prevent further optic nerve damage and to keep re-assessing for the need for any further surgical intervention. Subsequently, if the patient is keen and suitable, functional devices can be considered for cosmesis.

Cosmetic iris implant surgery represents a health hazard for the unsuspecting public, and the ophthalmic community/regulatory agencies of the countries in which the surgery is being done should strongly caution against their use. These countries should also make it mandatory to have a database capturing all patients who have had these devices and their complications.

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Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

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